

**TDMS No.** 20007 - 05

**Test Type:** CHRONIC

**Route:** GAVAGE

**Species/Strain:** RATS/F 344/N

**P04: NEOPLASMS BY INDIVIDUAL ANIMAL**

Kava kava extract

**CAS Number:** 9000-38-8

**Date Report Requested:** 09/21/2010

**Time Report Requested:** 09:10:56

**First Dose M/F:** 08/18/04 / 08/19/04

**Lab:** BAT

F2\_R2

**C Number:** C20007

**Lock Date:** 03/27/2007

**Cage Range:** ALL

**Date Range:** ALL

**Reasons For Removal:** ALL

**Removal Date Range:** ALL

**Treatment Groups:** Include ALL

**Study Gender:** Both

**TDMSE Version:** 2.2.0

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## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

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Lab: BAT

		DAY ON TEST	0 7 2 9	0 7 5 7	0 6 2 1	0 7 2 9	0 7 2 8	0 5 2 8	0 7 2 9	0 7 2 9	0 5 0 4	0 7 2 7	0 7 2 7	0 7 2 8	0 7 2 8	0 7 2 7	0 7 2 8	0 7 2 7	0 7 2 8	0 7 2 5				
		ANIMAL ID	0 0 0 0 1	0 0 0 0 2	0 0 0 0 3	0 0 0 0 4	0 0 0 0 5	0 0 0 0 6	0 0 0 0 7	0 0 0 0 8	0 1 1 1 0	1 1 1 1 1	1 1 1 1 4	1 1 1 1 5	1 1 1 1 6	1 1 1 1 7	1 1 1 1 8	1 1 1 1 9	1 1 1 1 0	1 1 1 1 1	1 1 1 1 2	1 1 1 1 3	1 1 1 1 4	males (cont...)

## ALIMENTARY SYSTEM

Esophagus

Intestine Large, Cecum

Intestine Large, Colon

Intestine Large, Rectum

Intestine Small, Duodenum

Intestine Small, Ileum  
Lymphoma Malignant

Intestine Small, Jejunum

Liver

Fibrous Histiocytoma, Metastatic, Skeletal  
Muscle

Hepatocellular Adenoma

Leukemia Mononuclear

Mesentery

Mesothelioma Malignant

Oral Mucosa

Squamous Cell Papilloma

Pancreas

Leukemia Mononuclear

+ +

+ +

+ +

+ +

+ +

+ +

+ +

+ +

X +

X X

+ +

X X

+ +

X

\* .. Total animals with tissue examined microscopically; Total animals with tumor

M .. Missing tissue

+ .. Tissue examined microscopically

A .. Autolysis precludes evaluation

X .. Lesion present

BLANK .. Not examined microscopically

I .. Insufficient tissue

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Lab: BAT

|  |          | DAY ON TEST | 0<br>7 | 0<br>7 | 0<br>6 | 0<br>7 | 0<br>6 | 0<br>6 | 0<br>7 | 0<br>7 | 0<br>7 | 0<br>5 | 0<br>7 | 0<br>7 | 0<br>5 | 0<br>7 | 0<br>7 | 0<br>7 | 0<br>7 | 0<br>7 | 0<br>7 | 0<br>5 |                    |
|--|----------|-------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------------------|
|  |          | ANIMAL ID   | 2<br>9 | 2<br>7 | 5<br>1 | 2<br>8 | 2<br>7 | 1<br>0 | 2<br>9 | 2<br>7 | 2<br>8 | 2<br>2 | 2<br>8 | 2<br>7 | 2<br>9 | 2<br>4 | 2<br>7 | 2<br>7 | 2<br>7 | 2<br>8 | 2<br>7 | 2<br>5 | males<br>(cont...) |
| FISCHER 344 RATS MALE                      | 0.0 G/KG |             | 0<br>1 | 0<br>2 | 0<br>3 | 0<br>4 | 0<br>5 | 0<br>6 | 0<br>7 | 0<br>8 | 0<br>9 | 0<br>0 | 0<br>1 |                    |
|  |          |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        | X      |                    |
| Acinus, Adenoma                            |          |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |                    |
| Salivary Glands                            |          |             | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      |                    |
| Stomach, Forestomach                       |          |             | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      |                    |
| Leukemia Mononuclear                       |          |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        | X      |                    |
| Stomach, Glandular                         |          |             | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      |                    |
| Tooth                                      |          |             | +      |        |        | +      |        |        | +      |        |        |        |        |        |        |        |        |        | +      |        |        | +      | +                  |
| <b>CARDIOVASCULAR SYSTEM</b>               |          |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |                    |
| Blood Vessel                               |          |             | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      |                    |
| Heart                                      |          |             | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      |                    |
| Leukemia Mononuclear                       |          |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        | X                  |
| <b>ENDOCRINE SYSTEM</b>                    |          |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |                    |
| Adrenal Cortex                             |          |             | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      |                    |
| Carcinoma                                  |          |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |                    |
| Fibrous Histiocytoma, Metastatic, Skeletal |          |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |                    |
| Muscle                                     |          |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |                    |
| Leukemia Mononuclear                       |          |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |                    |
|  |          |             | X      |        |        | X      |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |                    |
| Adrenal Medulla                            |          |             | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      |                    |
| Leukemia Mononuclear                       |          |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |                    |
| Pheochromocytoma Benign                    |          |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |                    |
| Bilateral, Pheochromocytoma Benign         |          |             | X      |        |        | X      |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |                    |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

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Lab: BAT

|                              |  | DAY ON TEST | 0<br>7     | 0<br>7 | 0<br>6 | 0<br>7 | 0<br>6 | 0<br>6 | 0<br>7 | 0<br>7 | 0<br>7 | 0<br>5 | 0<br>7 | 0<br>7 | 0<br>5 | 0<br>7 | 0<br>7 | 0<br>7 | 0<br>7 | 0<br>7 | 0<br>7 | 0<br>5 |  |
|------------------------------|--|-------------|------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--|
|                              |  | ANIMAL ID   | 2<br>2     | 2<br>2 | 5<br>5 | 2<br>2 | 2<br>1 | 2<br>2 | 2<br>2 | 2<br>2 | 2<br>2 | 8<br>2 | 2<br>2 |  |
|                              |  |             | 9<br>7     | 7<br>7 | 1<br>1 | 8<br>8 | 7<br>0 | 9<br>9 | 7<br>7 | 8<br>8 | 7<br>7 | 2<br>2 |  |
| <b>FISCHER 344 RATS MALE</b> |  |             | 0<br>1     | 0<br>1 | 0<br>0 |  |
| <b>0.0 G/KG</b>              |  |             | 2<br>1     | 2<br>2 | 5<br>3 | 2<br>4 | 2<br>5 | 1<br>6 | 2<br>7 | 2<br>8 | 1<br>9 | 2<br>9 | 2<br>8 | 2<br>7 | 2<br>6 | 2<br>5 | 2<br>4 | 2<br>3 | 2<br>2 | 2<br>1 | 2<br>0 | 2<br>1 |  |
|                              |  |             | 9<br>2     | 9<br>2 | 7<br>5 | 8<br>2 | 7<br>2 | 0<br>1 | 9<br>2 | 8<br>2 | 7<br>2 | 8<br>2 | 7<br>2 |  |
|                              |  |             | 7<br>7     | 7<br>7 | 1<br>1 | 8<br>8 | 7<br>0 | 9<br>9 | 7<br>7 | 8<br>8 | 7<br>7 | 2<br>2 |  |
|                              |  |             | 5<br>5     | 5<br>5 | 4<br>4 |  |
|                              |  |             | 0<br>0     | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 |  |
|                              |  |             | 0<br>0     | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 |  |
|                              |  |             | 0<br>0     | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 |  |
|                              |  |             | 0<br>1     | 0<br>1 | 0<br>0 |  |
|                              |  |             | 0<br>1     | 0<br>2 | 0<br>3 | 0<br>4 | 0<br>5 | 0<br>6 | 0<br>7 | 0<br>8 | 0<br>9 | 0<br>0 | 0<br>1 | 0<br>2 | 0<br>3 | 0<br>4 | 0<br>5 | 0<br>6 | 0<br>7 | 0<br>8 | 0<br>9 | 0<br>0 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5     | 0<br>5 | 0<br>4 |  |
|                              |  |             | 0<br>5</td |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |  |

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First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

|                                       |          | DAY ON TEST | 0<br>7<br>2<br>9      | 0<br>7<br>5<br>7      | 0<br>6<br>2<br>1      | 0<br>7<br>2<br>9      | 0<br>7<br>2<br>8      | 0<br>5<br>2<br>2      | 0<br>7<br>2<br>9      | 0<br>7<br>2<br>8      | 0<br>5<br>2<br>4      | 0<br>7<br>2<br>7      | 0<br>7<br>2<br>8      | 0<br>7<br>2<br>7      | 0<br>7<br>2<br>8      | 0<br>7<br>2<br>7      | 0<br>7<br>2<br>8      | 0<br>7<br>2<br>5      | 0<br>0<br>0<br>0      | males<br>(cont...)    |                       |                       |                       |   |  |  |
|---------------------------------------|----------|-------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|---|--|--|
|                                       |          | ANIMAL ID   | 0<br>0<br>0<br>0<br>1 | 0<br>0<br>0<br>0<br>2 | 0<br>0<br>0<br>0<br>3 | 0<br>0<br>0<br>0<br>4 | 0<br>0<br>0<br>0<br>5 | 0<br>0<br>0<br>0<br>6 | 0<br>0<br>0<br>0<br>7 | 0<br>0<br>0<br>0<br>8 | 0<br>0<br>0<br>0<br>9 | 0<br>0<br>0<br>0<br>0 | 0<br>0<br>0<br>0<br>1 | 0<br>0<br>0<br>0<br>1 | 0<br>0<br>0<br>0<br>2 | 0<br>0<br>0<br>0<br>3 | 0<br>0<br>0<br>0<br>4 | 0<br>0<br>0<br>0<br>5 | 0<br>0<br>0<br>0<br>6 | 0<br>0<br>0<br>0<br>7 | 0<br>0<br>0<br>0<br>8 | 0<br>0<br>0<br>0<br>9 | 0<br>0<br>0<br>0<br>0 |   |  |  |
| FISCHER 344 RATS MALE                 | 0.0 G/KG |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |   |  |  |
| Seminal Vesicle                       |          |             | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | + |  |  |
| Testes                                |          |             | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | + |  |  |
| Mesothelioma Malignant                |          |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |   |  |  |
| Bilateral, Interstitial Cell, Adenoma |          |             |                       |                       | X                     | X                     | X                     | X                     | X                     | X                     | X                     | X                     | X                     | X                     | X                     | X                     | X                     | X                     | X                     | X                     | X                     | X                     | X                     | X |  |  |
| Interstitial Cell, Adenoma            |          |             |                       |                       | X                     | X                     | X                     | X                     | X                     | X                     | X                     | X                     | X                     | X                     | X                     | X                     | X                     | X                     | X                     | X                     | X                     | X                     | X                     | X |  |  |
| <b>HEMATOPOIETIC SYSTEM</b>           |          |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |   |  |  |
| Bone Marrow                           |          |             | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | + |  |  |
| Lymph Node                            |          |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |   |  |  |
| Deep Cervical, Leukemia Mononuclear   |          |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |   |  |  |
| Lymph Node, Mandibular                |          |             | M                     | M                     | M                     | M                     | M                     | M                     | M                     | M                     | M                     | M                     | M                     | M                     | M                     | M                     | M                     | M                     | M                     | M                     | M                     | M                     | M                     | M |  |  |
| Lymph Node, Mesenteric                |          |             | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | + |  |  |
| Leukemia Mononuclear                  |          |             |                       |                       | X                     |                       |                       | X                     |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |   |  |  |
| Lymphoma Malignant                    |          |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |   |  |  |
| Spleen                                |          |             | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | + |  |  |
| Leukemia Mononuclear                  |          |             |                       |                       | X                     |                       |                       | X                     |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |   |  |  |
| Thymus                                |          |             | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | + |  |  |
| Leukemia Mononuclear                  |          |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |   |  |  |
| <b>INTEGUMENTARY SYSTEM</b>           |          |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |   |  |  |
| Mammary Gland                         |          |             | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | + |  |  |
| Skin                                  |          |             | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | + |  |  |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

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Lab: BAT

|                              |  | DAY ON TEST | 0<br>7 | 0<br>7 | 0<br>6 | 0<br>7 | 0<br>6 | 0<br>6 | 0<br>7 | 0<br>7 | 0<br>7 | 0<br>7 | 0<br>5 | 0<br>7 | 0<br>5 | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                              |  | ANIMAL ID   | 2<br>9 | 2<br>7 | 5<br>1 | 2<br>8 | 2<br>7 | 1<br>0 | 2<br>9 | 2<br>7 | 2<br>8 | 2<br>7 | 2<br>8 | 2<br>7 | 2<br>9 | 2<br>7 | 2<br>7 | 2<br>7 | 2<br>7 | 2<br>7 | 2<br>5 |
| <b>FISCHER 344 RATS MALE</b> |  |             | 0<br>0 |
| <b>0.0 G/KG</b>              |  |             | 0<br>0 |
|                              |  |             | 0<br>0 |
|                              |  |             | 0<br>1 | 0<br>2 | 0<br>3 | 0<br>4 | 0<br>5 | 0<br>6 | 0<br>7 | 0<br>8 | 0<br>9 | 0<br>0 | 1<br>1 | 1<br>2 | 1<br>3 | 1<br>4 | 1<br>5 | 1<br>6 | 1<br>7 | 1<br>8 | 1<br>9 |
|                              |  |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |

Mesothelioma Malignant

X

males  
(cont...)

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

**Test Type: CHRONIC**

## **Route: GAVAGE**

**Species/Strain:** RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

#### Kava kava extract

CAS Number: 9000-38-8

**Date Report Requested:** 09/21/2010

**Time Report Requested:** 09:10:56

**First Dose M/F:** 08/18/04 / 08/19/04

## Lab: BAT

| FISCHER 344 RATS MALE | 0.0 G/KG | ANIMAL ID | DAY ON TEST |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
|-----------------------|----------|-----------|-------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
|                       |          |           | 07          | 07 | 07 | 06 | 07 | 06 | 05 | 07 | 06 | 07 | 07 | 07 | 07 | 05 | 07 | 07 | 05 | 07 | 06 | 06 | 07 | 07 | 06 | 06 |
|                       |          |           | 28          | 28 | 29 | 38 | 29 | 44 | 11 | 88 | 99 | 88 | 77 | 88 | 77 | 88 | 44 | 88 | 77 | 44 | 77 | 55 | 66 | 77 | 22 | 77 |
|                       |          |           | 00          | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 |
|                       |          |           | 00          | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 |
|                       |          |           | 22          | 22 | 22 | 22 | 33 | 33 | 33 | 33 | 33 | 33 | 33 | 33 | 33 | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 55 |
|                       |          |           | 66          | 77 | 88 | 99 | 00 | 11 | 22 | 33 | 44 | 55 | 77 | 88 | 99 | 00 | 11 | 22 | 33 | 44 | 55 | 66 | 77 | 88 | 99 | 00 |

# ALIMENTARY SYSTEM

\* .. Total animals with tissue examined microscopically: Total animals with tumor

+ .. Tissue examined microscopically

X., Lesion present

#### I .. Insufficient tissue

M .. Missing tissue

#### A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

| FISCHER 344 RATS MALE        | 0.0 G/KG | DAY ON TEST                                |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |   |    | * TOTALS |
|------------------------------|----------|--|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|---|----|----------|
|                              |          |  | 0<br>7<br>2<br>8           | 0<br>7<br>2<br>8           | 0<br>6<br>0<br>9           | 0<br>1<br>2<br>3           | 0<br>7<br>2<br>8           | 0<br>5<br>1<br>4           | 0<br>7<br>1<br>8           | 0<br>6<br>9<br>9           | 0<br>7<br>2<br>8           | 0<br>7<br>2<br>8           | 0<br>7<br>2<br>8           | 0<br>5<br>0<br>4           | 0<br>7<br>2<br>8           | 0<br>7<br>2<br>7           | 0<br>5<br>2<br>4           | 0<br>7<br>2<br>7           | 0<br>6<br>2<br>5           | 0<br>6<br>8<br>6           | 0<br>7<br>2<br>7           | 0<br>6<br>2<br>7           | 0<br>7<br>2<br>7           | 0<br>6<br>2<br>7           | 0<br>7<br>2<br>7           |   |    |          |
| ANIMAL ID                    |          |  | 0<br>0<br>0<br>0<br>2<br>6 | 0<br>0<br>0<br>0<br>2<br>7 | 0<br>0<br>0<br>0<br>3<br>9 | 0<br>0<br>0<br>0<br>3<br>0 | 0<br>0<br>0<br>0<br>3<br>1 | 0<br>0<br>0<br>0<br>3<br>2 | 0<br>0<br>0<br>0<br>3<br>3 | 0<br>0<br>0<br>0<br>3<br>4 | 0<br>0<br>0<br>0<br>3<br>5 | 0<br>0<br>0<br>0<br>3<br>7 | 0<br>0<br>0<br>0<br>3<br>8 | 0<br>0<br>0<br>0<br>3<br>9 | 0<br>0<br>0<br>0<br>4<br>0 | 0<br>0<br>0<br>0<br>4<br>1 | 0<br>0<br>0<br>0<br>4<br>2 | 0<br>0<br>0<br>0<br>4<br>3 | 0<br>0<br>0<br>0<br>4<br>4 | 0<br>0<br>0<br>0<br>4<br>5 | 0<br>0<br>0<br>0<br>4<br>6 | 0<br>0<br>0<br>0<br>4<br>7 | 0<br>0<br>0<br>0<br>4<br>8 | 0<br>0<br>0<br>0<br>4<br>9 | 0<br>0<br>0<br>0<br>5<br>0 |   |    |          |
|                              |          | Acinus, Adenoma                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |   |    | 1        |
|                              |          | Salivary Glands                            | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | + | 49 |          |
|                              |          | Stomach, Forestomach                       | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | + | 49 |          |
|                              |          | Leukemia Mononuclear                       |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |   |    | 1        |
|                              |          | Stomach, Glandular                         | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | + | 49 |          |
|                              |          | Tooth                                      |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |   |    | 10       |
| <b>CARDIOVASCULAR SYSTEM</b> |          |  |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |   |    |          |
|                              |          | Blood Vessel                               | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | + | 49 |          |
|                              |          | Heart                                      | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | + | 49 |          |
|                              |          | Leukemia Mononuclear                       |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |   |    | 2        |
| <b>ENDOCRINE SYSTEM</b>      |          |  |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |   |    |          |
|                              |          | Adrenal Cortex                             | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | + | 49 |          |
|                              |          | Carcinoma                                  |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |   |    | 1        |
|                              |          | Fibrous Histiocytoma, Metastatic, Skeletal |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |   |    | 1        |
|                              |          | Muscle                                     |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |   |    | 3        |
|                              |          | Leukemia Mononuclear                       |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |   |    | 3        |
|                              |          | X  |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |   |    |          |
|                              |          | Adrenal Medulla                            | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | + | 49 |          |
|                              |          | Leukemia Mononuclear                       |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |   |    | 3        |
|                              |          | Pheochromocytoma Benign                    |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |   |    | 4        |
|                              |          | Bilateral, Pheochromocytoma Benign         |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |   |    | 1        |
|                              |          | X  |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |   |    |          |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

| FISCHER 344 RATS MALE                                       | 0.0 G/KG | DAY ON TEST |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |               |
|---|----------|-------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|---|---|---------------|
|   |          |             | 0<br>7<br>2<br>8 | 0<br>7<br>2<br>8 | 0<br>6<br>1<br>9 | 0<br>7<br>2<br>9 | 0<br>6<br>1<br>4 | 0<br>5<br>1<br>1 | 0<br>7<br>2<br>8 | 0<br>6<br>9<br>8 | 0<br>7<br>2<br>8 | 0<br>7<br>2<br>7 | 0<br>7<br>2<br>8 | 0<br>5<br>2<br>4 | 0<br>7<br>2<br>8 | 0<br>7<br>2<br>7 | 0<br>5<br>2<br>4 | 0<br>7<br>2<br>7 | 0<br>6<br>2<br>5 | 0<br>6<br>8<br>6 | 0<br>7<br>2<br>7 | 0<br>6<br>8<br>7 | 0<br>7<br>2<br>7 | 0<br>6<br>8<br>7 |   |   |               |
| ANIMAL ID   |          | * TOTALS    |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |               |
|   |          |             |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |               |
| Islets, Pancreatic Adenoma                                  |          | +           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | + | 49<br>4       |
| Parathyroid Gland Adenoma                                   |          | +           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | + | 49<br>1       |
| Pituitary Gland Leukemia Mononuclear Pars Distalis, Adenoma |          | +           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | + | 49<br>2<br>21 |
| Thyroid Gland C-cell, Adenoma Follicular Cell, Adenoma      |          | +           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | + | 49<br>8<br>1  |

## GENERAL BODY SYSTEM

NONE

## GENITAL SYSTEM

|                                   |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |         |   |
|-----------------------------------|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---------|---|
| Coagulating Gland                 |  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | +       | 2 |
| Epididymis Mesothelioma Malignant |  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | X | 49<br>3 |   |
| Preputial Gland Carcinoma         |  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | X | 49<br>1 |   |
| Prostate                          |  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49      |   |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

**Test Type: CHRONIC**

## **Route: GAVAGE**

**Species/Strain:** RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

### Kaya kaya extract

CAS Number: 9000-38-8

**Date Report Requested:** 09/21/2010

**Time Report Requested:** 09:10:56

**First Dose M/F:** 08/18/04 / 08/19/04

## Lab: BAT

## **INTEGUMENTARY SYSTEM**

\* Total animals with tissue examined microscopically: Total animals with tumor

± = Tissue examined microscopically

X Lesion present

✓ .. Lesion present

M - Missing tissue

A - Autolysis precludes evaluation

BLANK Not examined microscopically



TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

|   |  | DAY ON TEST | 0<br>7          | 0<br>7 | 0<br>7 | 0<br>6 | 0<br>7 | 0<br>6 | 0<br>5 | 0<br>7 | 0<br>6 | 0<br>7 | 0<br>7 | 0<br>7 | 0<br>5 | 0<br>7 | 0<br>7 | 0<br>5 | 0<br>7 | 0<br>6 | 0<br>6 | 0<br>7 | 0<br>7 |        |        |        |
|---|--|-------------|-----------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|
|   |  | ANIMAL ID   | 2<br>2          | 2<br>8 | 0<br>8 | 1<br>9 | 2<br>9 | 2<br>4 | 1<br>1 | 8<br>8 | 9<br>9 | 2<br>8 | 2<br>8 | 2<br>7 | 2<br>8 | 2<br>8 | 2<br>4 | 2<br>8 | 2<br>7 | 2<br>4 | 2<br>7 | 5<br>6 | 7<br>7 | 8<br>7 | 2<br>7 | 2<br>7 |
| <b>FISCHER 344 RATS MALE</b>                      |  |             | 0<br>0          | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 |        |
| <b>0.0 G/KG</b>                                   |  |             | 0<br>0          | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 |        |
|   |  |             | 0<br>0          | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 |        |
|   |  |             | 2<br>2          | 2<br>2 | 2<br>2 | 2<br>3 | 3<br>3 | 3<br>4 | 4<br>4 | 4<br>4 | 4<br>4 | 4<br>4 | 4<br>5 | 6<br>6 | 7<br>7 | 8<br>8 | 9<br>9 |        |
|   |  |             | 6<br>6          | 7<br>7 | 8<br>8 | 9<br>9 | 0<br>0 | 1<br>1 | 2<br>2 | 3<br>3 | 4<br>4 | 5<br>5 | 7<br>7 | 8<br>8 | 9<br>9 | 0<br>0 | 1<br>1 | 2<br>2 | 3<br>3 | 4<br>4 | 5<br>5 | 6<br>6 | 7<br>7 | 8<br>8 | 9<br>9 | 0<br>0 |
|   |  |             | <b>* TOTALS</b> |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |
| Fibrous Histiocytoma, Metastatic, Skeletal Muscle |  |             |                 |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |
| Leukemia Mononuclear                              |  |             | X               |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |
| Mediastinum, Osteosarcoma, Metastatic, Bone       |  |             |                 |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |
| Nose  |  |             | +               |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |
| Trachea   |  |             | +               |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |
| <b>SPECIAL SENSES SYSTEM</b>                      |  |             |                 |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |
| Eye   |  |             | +               |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |
| Harderian Gland                                   |  |             | +               |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |
| <b>URINARY SYSTEM</b>                             |  |             |                 |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |
| Kidney  |  |             | +               |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |
| Leukemia Mononuclear                              |  |             | +               |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |
| Ureter  |  |             | X               |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |
| Urethra   |  |             |                 |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |
| Urinary Bladder                                   |  |             | +               |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |
| <b>SYSTEMIC LESIONS</b>                           |  |             |                 |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |
| Multiple Organ                                    |  |             | +               |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |
| Leukemia Mononuclear                              |  |             | +               |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |
| Lymphoma Malignant                                |  |             | X               |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

|                        |  | DAY ON TEST           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |          |   |   |
|------------------------|--|-----------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|----------|---|---|
|                        |  | FISCHER 344 RATS MALE |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |          |   |   |
|                        |  | 0.0 G/KG              |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |          |   |   |
|                        |  | ANIMAL ID             |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |          |   |   |
|                        |  | 0<br>7<br>2<br>8      | 0<br>7<br>2<br>8 | 0<br>6<br>1<br>9 | 0<br>7<br>2<br>9 | 0<br>6<br>1<br>4 | 0<br>5<br>1<br>1 | 0<br>7<br>2<br>8 | 0<br>6<br>9<br>9 | 0<br>7<br>2<br>8 | 0<br>7<br>2<br>7 | 0<br>7<br>2<br>8 | 0<br>5<br>2<br>4 | 0<br>7<br>2<br>8 | 0<br>7<br>2<br>7 | 0<br>5<br>2<br>4 | 0<br>7<br>2<br>7 | 0<br>6<br>2<br>5 | 0<br>6<br>2<br>7 | 0<br>6<br>2<br>7 | 0<br>7<br>2<br>7 |          |   |   |
|                        |  | 0<br>0<br>0<br>0      | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | * TOTALS |   |   |
| Mesothelioma Malignant |  |                       |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  | X        | X | 3 |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

**Test Type: CHRONIC**

## **Route: GAVAGE**

**Species/Strain:** RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

## Kava kava extract

**CAS Number:** 9000-38-8

**Date Report Requested:** 09/21/2010

**Time Report Requested:** 09:10:56

**First Dose M/F:** 08/18/04 / 08/19/04

## Lab: BAT

| FISCHER 344 RATS MALE | 0.1 G/KG | DAY ON TEST |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     | males<br>(cont...) |     |                    |
|-----------------------|----------|-------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|--------------------|-----|--------------------|
|                       |          |             | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0                  |     |                    |
| ANIMAL ID             | 077      | 077         | 077 | 077 | 077 | 077 | 077 | 077 | 067 | 077 | 067 | 077 | 067 | 077 | 067 | 077 | 067 | 077 | 067 | 077 | 067 | 077 | 067                | 077 | males<br>(cont...) |
|                       |          | 28          | 7   | 7   | 7   | 7   | 4   | 7   | 9   | 9   | 8   | 9   | 8   | 8   | 1   | 8   | 8   | 9   | 7   | 8   | 8   | 9   | 7                  | 4   |                    |
|                       |          | 0           | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0                  | 0   |                    |
|                       |          | 0           | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0                  | 0   |                    |
|                       |          | 0           | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0   | 0                  | 0   |                    |
|                       |          | 5           | 5   | 5   | 5   | 5   | 5   | 5   | 5   | 5   | 5   | 6   | 6   | 6   | 6   | 6   | 6   | 6   | 6   | 6   | 7   | 7   | 7                  | 7   |                    |
|                       |          | 1           | 2   | 3   | 4   | 5   | 6   | 7   | 8   | 9   | 0   | 1   | 2   | 3   | 4   | 5   | 6   | 7   | 8   | 9   | 0   | 1   | 2                  | 3   |                    |

## **ALIMENTARY SYSTEM**

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

### I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

**Test Type: CHRONIC**

## **Route: GAVAGE**

**Species/Strain:** RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

## Kava kava extract

CAS Number: 9000-38-8

**Date Report Requested:** 09/21/2010

**Time Report Requested:** 09:10:56

**First Dose M/F:** 08/18/04 / 08/19/04

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TDMS No. 20007 - 05

**Test Type: CHRONIC**

## **Route: GAVAGE**

**Species/Strain:** RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

## Kava kava extract

CAS Number: 9000-38-8

**Date Report Requested:** 09/21/2010

**Time Report Requested:** 09:10:56

**First Dose M/F:** 08/18/04 / 08/19/04

## Lab: BAT

## **GENERAL BODY SYSTEM**

## Tissue NOS Rhabdomyosarcoma

## **GENITAL SYSTEM**

## Coagulating Gland

Epididymis  
Fibrous Histiocytoma, Metastatic, Skin  
Mesothelioma Malignant

Preputial Gland  
Carcinoma  
Schwannoma Malignant

## Prostate Adenoma

## Seminal Vesicle

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

### I .. Insufficient tissue

#### M - Missing tissue

#### A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically



TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

DAY ON TEST

|        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |
|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|
| 0<br>7 |        |        |
| 2<br>8 | 2<br>7 | 2<br>7 | 2<br>7 | 1<br>4 | 2<br>7 | 2<br>9 | 2<br>9 | 8<br>8 | 9<br>8 | 9<br>8 | 8<br>8 | 8<br>8 | 1<br>1 | 5<br>8 | 7<br>8 | 7<br>8 | 7<br>9 | 7<br>7 | 7<br>8 | 7<br>8 | 7<br>3 | 7<br>9 | 6<br>4 |        |
| 0<br>0 |        |
| 0<br>0 |        |
| 5<br>1 | 5<br>2 | 5<br>3 | 5<br>4 | 5<br>5 | 5<br>6 | 5<br>7 | 5<br>8 | 5<br>9 | 5<br>0 | 5<br>1 | 5<br>2 | 5<br>3 | 5<br>4 | 5<br>5 | 5<br>6 | 5<br>7 | 5<br>8 | 5<br>9 | 5<br>0 | 5<br>1 | 5<br>2 | 5<br>3 | 5<br>4 | 5<br>5 |

males  
(cont...)**FISCHER 344 RATS MALE****0.1 G/KG**

ANIMAL ID

Fibroadenoma

X

Skin

Subcutaneous Tissue, Fibroma

Subcutaneous Tissue, Fibrous Histiocytoma

Subcutaneous Tissue, Osteosarcoma

X

**MUSCULOSKELETAL SYSTEM**

Bone

Osteosarcoma

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
| X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |

**NERVOUS SYSTEM**

Brain

Leukemia Mononuclear

Meningioma Malignant

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
| X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |

**RESPIRATORY SYSTEM**

Lung

Alveolar/Bronchiolar Carcinoma

Carcinoma, Metastatic, Salivary Glands

Fibrous Histiocytoma, Metastatic, Skin

Leukemia Mononuclear

Mesothelioma Malignant

Neural Crest Tumor, Metastatic, Ear

Osteosarcoma, Metastatic, Skin

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
| X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |

Nose

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
| X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

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TDMS No. 20007 - 05

**Test Type: CHRONIC**

## **Route: GAVAGE**

**Species/Strain:** RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kaya kaya extract

**CAS Number:** 9000-38-8

**Date Report Requested:** 09/21/2010

**Time Report Requested:** 09:10:56

**First Dose M/F:** 08/18/04 / 08/19/04

## Lab: BAT

| FISCHER 344 RATS MALE |   | 0.1 G/KG | ANIMAL ID | DAY ON TEST |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-----------------------|---|----------|-----------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                       |   |          |           | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0                     | 7 | 7        | 7         | 7           | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| 3                     | 2 | 2        | 2         | 2           | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| 0                     | 7 | 8        | 9         | 8           | 9 | 8 | 9 | 8 | 9 | 9 | 8 | 9 | 8 | 7 | 8 | 6 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| 0                     | 0 | 0        | 0         | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0                     | 0 | 0        | 0         | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0                     | 0 | 0        | 0         | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7                     | 7 | 7        | 7         | 7           | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 |
| 6                     | 7 | 8        | 9         | 0           | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 9 | 0 |

# ALIMENTARY SYSTEM

\* .. Total animals with tissue examined microscopically; Total animals with tumor

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TDMS No. 20007 - 05

Test Type: CHRONIC

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Kava kava extract

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Lab: BAT

| FISCHER 344 RATS MALE                  | 0.1 G/KG | DAY ON TEST | ANIMAL ID |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |    | * TOTALS |
|--|----------|-------------|-----------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|---|---|----|----------|
|  |          |             |           | 0<br>0<br>3<br>0 | 0<br>7<br>2<br>0 | 0<br>7<br>2<br>8 | 0<br>7<br>2<br>9 | 0<br>5<br>2<br>5 | 0<br>7<br>2<br>7 | 0<br>6<br>4<br>8 | 0<br>7<br>2<br>6 | 0<br>7<br>2<br>7 | 0<br>7<br>2<br>9 | 0<br>7<br>2<br>7 | 0<br>7<br>2<br>7 | 0<br>5<br>2<br>7 | 0<br>7<br>2<br>8 | 0<br>6<br>1<br>5 | 0<br>7<br>2<br>8 | 0<br>6<br>1<br>5 | 0<br>7<br>2<br>8 | 0<br>6<br>1<br>5 | 0<br>7<br>2<br>8 | 0<br>7<br>2<br>7 |   |   |    |          |
| Salivary Glands                        |          |             |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | + | 50 |          |
| Carcinoma                              |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   | 1  |          |
| Stomach, Forestomach                   |          |             |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | + | 50 |          |
| Stomach, Glandular                     |          |             |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | + | 50 |          |
| Tooth                                  |          |             |           |                  | +                | +                |                  | +                |                  | +                |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   | 6  |          |
| <b>CARDIOVASCULAR SYSTEM</b>           |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |    |          |
| Blood Vessel                           |          |             |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | + | 50 |          |
| Heart                                  |          |             |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | + | 50 |          |
| Fibrous Histiocytoma, Metastatic, Skin |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |    | 1        |
| Leukemia Mononuclear                   |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |    | X        |
| <b>ENDOCRINE SYSTEM</b>                |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |    |          |
| Adrenal Cortex                         |          |             |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | + | 50 |          |
| Leukemia Mononuclear                   |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |    | 1        |
| Adrenal Medulla                        |          |             |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | + | 50 |          |
| Pheochromocytoma Benign                |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |    | 8        |
| Pheochromocytoma Malignant             |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |    | 2        |
| Islets, Pancreatic                     |          |             |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | + | 50 |          |
| Adenoma                                |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |    | 2        |
| Parathyroid Gland                      |          |             |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | + | 50 |          |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

**Test Type: CHRONIC**

## **Route: GAVAGE**

**Species/Strain:** RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

#### Kava kava extract

**CAS Number:** 9000-38-8

**Date Report Requested:** 09/21/2010

**Time Report Requested:** 09:10:56

**First Dose M/F:** 08/18/04 / 08/19/04

## Lab: BAT

**\* TOTALS**

## **GENERAL BODY SYSTEM**

Tissue NOS + 1  
Rhabdomyosarcoma X 1

# **GENITAL SYSTEM**

|  |   |   |    |
|--|---|---|----|
| Coagulating Gland                      |   | + | 2  |
| Epididymis                             | + | + | 50 |
| Fibrous Histiocytoma, Metastatic, Skin |   |   | 1  |
| Mesothelioma Malignant                 |   | X | 3  |
| Preputial Gland                        | + | + | 50 |
| Carcinoma                              |   | X | 1  |
| Schwannoma Malignant                   |   |   | 1  |
| Prostate                               | + | + | 50 |
| Adenoma                                |   | X | 1  |
| Seminal Vesicle                        | + | + | 50 |

\* .. Total animals with tissue examined microscopically: Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

### I .. Insufficient tissue

M .. Missing tissue

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TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

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## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

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First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

|                                       |          | DAY ON TEST | 0<br>0<br>3<br>0           | 0<br>7<br>2<br>0           | 0<br>7<br>2<br>8           | 0<br>7<br>2<br>9           | 0<br>5<br>2<br>5           | 0<br>7<br>2<br>7           | 0<br>6<br>4<br>8           | 0<br>7<br>2<br>6           | 0<br>7<br>2<br>7           | 0<br>7<br>2<br>9           | 0<br>7<br>2<br>7           | 0<br>7<br>2<br>9           | 0<br>7<br>2<br>7           | 0<br>5<br>2<br>7           | 0<br>7<br>2<br>8           | 0<br>6<br>1<br>5           | 0<br>7<br>2<br>8           | 0<br>7<br>2<br>7           | 0<br>7<br>2<br>7           |          |    |    |   |
|---------------------------------------|----------|-------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------|----|----|---|
|                                       |          | ANIMAL ID   | 0<br>0<br>0<br>0<br>7<br>6 | 0<br>0<br>0<br>0<br>7<br>7 | 0<br>0<br>0<br>0<br>8<br>8 | * TOTALS |    |    |   |
| FISCHER 344 RATS MALE                 | 0.1 G/KG |             | 0<br>0<br>3<br>0           | 0<br>7<br>2<br>0           | 0<br>7<br>2<br>8           | 0<br>7<br>2<br>9           | 0<br>5<br>2<br>5           | 0<br>7<br>2<br>7           | 0<br>6<br>4<br>8           | 0<br>7<br>2<br>6           | 0<br>7<br>2<br>7           | 0<br>7<br>2<br>9           | 0<br>7<br>2<br>7           | 0<br>7<br>2<br>9           | 0<br>7<br>2<br>7           | 0<br>5<br>2<br>7           | 0<br>7<br>2<br>8           | 0<br>6<br>1<br>5           | 0<br>7<br>2<br>8           | 0<br>7<br>2<br>7           | 0<br>7<br>2<br>7           |          |    |    |   |
| Testes                                |          |             | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +        | 50 |    |   |
| Mesothelioma Malignant                |          |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |          |    | 3  |   |
| Bilateral, Interstitial Cell, Adenoma |          |             | X                          | X                          | X                          | X                          |                            |                            |                            | X                          | X                          | X                          | X                          | X                          | X                          | X                          | X                          | X                          | X                          | X                          | X                          | X        | 32 |    |   |
| Interstitial Cell, Adenoma            |          |             |                            |                            | X                          | X                          | X                          | X                          | X                          |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |          | 12 |    |   |
| <b>HEMATOPOIETIC SYSTEM</b>           |          |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |          |    |    |   |
| Bone Marrow                           |          |             | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +        | +  | 50 |   |
| Mast Cell Tumor Malignant             |          |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |          |    |    | 1 |
| Lymph Node                            |          |             |                            |                            |                            |                            | +                          |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |          |    |    | 3 |
| Pancreatic, Leukemia Mononuclear      |          |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |          |    |    | 1 |
| Pancreatic, Mast Cell Tumor Malignant |          |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |          |    |    | 1 |
| Lymph Node, Mandibular                |          |             | M                          | M                          | M                          | M                          | M                          | M                          | M                          | M                          | M                          | M                          | M                          | M                          | M                          | M                          | M                          | M                          | M                          | M                          | M                          | M        | M  | 0  |   |
| Lymph Node, Mesenteric                |          |             | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +        | +  | 50 |   |
| Leukemia Mononuclear                  |          |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |          |    |    | 2 |
| Mast Cell Tumor Malignant             |          |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |          |    |    | 1 |
| Spleen                                |          |             | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +        | +  | 50 |   |
| Leukemia Mononuclear                  |          |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |          |    |    | 8 |
| Mast Cell Tumor Malignant             |          |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |          |    |    | 1 |
| Thymus                                |          |             | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +        | +  | 50 |   |
| Mesothelioma Malignant                |          |             |                            |                            |                            |                            | X                          |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |          |    |    | 1 |
| <b>INTEGUMENTARY SYSTEM</b>           |          |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |          |    |    |   |
| Mammary Gland                         |          |             | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +        | +  | 50 |   |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

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TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

**P04: NEOPLASMS BY INDIVIDUAL ANIMAL**

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

| FISCHER 344 RATS MALE                     | 0.1 G/KG | DAY ON TEST |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                  |                  | * TOTALS |   |   |
|---|----------|-------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|------------------|------------------|----------|---|---|
|   |          |             | 0<br>0<br>3<br>0           | 0<br>7<br>2<br>0           | 0<br>7<br>2<br>8           | 0<br>7<br>2<br>9           | 0<br>5<br>2<br>5           | 0<br>7<br>2<br>7           | 0<br>6<br>4<br>6           | 0<br>7<br>2<br>9           | 0<br>7<br>2<br>7           | 0<br>6<br>2<br>5           | 0<br>7<br>2<br>8           | 0<br>7<br>2<br>7 | 0<br>6<br>2<br>7 |          |   |   |
| ANIMAL ID                                 |          |             | 0<br>0<br>0<br>0<br>7<br>6 | 0<br>0<br>0<br>0<br>7<br>7 | 0<br>0<br>0<br>0<br>8<br>8 | 0<br>0<br>0<br>0<br>8<br>9 | 0<br>0<br>0<br>0<br>8<br>3 | 0<br>0<br>0<br>0<br>8<br>4 | 0<br>0<br>0<br>0<br>8<br>5 | 0<br>0<br>0<br>0<br>8<br>6 | 0<br>0<br>0<br>0<br>8<br>7 | 0<br>0<br>0<br>0<br>8<br>8 | 0<br>0<br>0<br>0<br>8<br>9 | 0<br>0<br>0<br>0<br>9<br>0 | 0<br>0<br>0<br>0<br>9<br>1 | 0<br>0<br>0<br>0<br>9<br>2 | 0<br>0<br>0<br>0<br>9<br>3 | 0<br>0<br>0<br>0<br>9<br>4 | 0<br>0<br>0<br>0<br>9<br>5 | 0<br>0<br>0<br>0<br>9<br>6 | 0<br>0<br>0<br>0<br>9<br>7 | 0<br>0<br>0<br>0<br>9<br>8 | 0<br>0<br>0<br>0<br>9<br>9 | 0<br>0<br>0<br>0<br>0<br>0 |                  |                  |          |   |   |
| Fibroadenoma                              |          |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                  |                  |          | 1 |   |
| Skin                                      |          |             | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                | +                | 50       |   |   |
| Subcutaneous Tissue, Fibroma              |          |             |                            |                            | X                          |                            | X                          |                            | X                          |                            | X                          |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                  |                  |          | 5 |   |
| Subcutaneous Tissue, Fibrous Histiocytoma |          |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                  |                  |          |   | 1 |
| Subcutaneous Tissue, Osteosarcoma         |          |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                  |                  |          |   | 1 |
| <b>MUSCULOSKELETAL SYSTEM</b>             |          |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                  |                  |          |   |   |
| Bone                                      |          |             | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                | +                | 50       |   |   |
| Osteosarcoma                              |          |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                  |                  |          |   | 1 |
| <b>NERVOUS SYSTEM</b>                     |          |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                  |                  |          |   |   |
| Brain                                     |          |             | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                | +                | 50       |   |   |
| Leukemia Mononuclear                      |          |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                  |                  |          |   | 1 |
| Meningioma Malignant                      |          |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                  |                  |          |   | 1 |
| <b>RESPIRATORY SYSTEM</b>                 |          |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                  |                  |          |   |   |
| Lung                                      |          |             | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                | +                | 50       |   |   |
| Alveolar/Bronchiolar Carcinoma            |          |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                  |                  |          |   | 1 |
| Carcinoma, Metastatic, Salivary Glands    |          |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                  |                  |          |   | 1 |
| Fibrous Histiocytoma, Metastatic, Skin    |          |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                  |                  |          |   | 1 |
| Leukemia Mononuclear                      |          |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                  |                  |          |   | 4 |
| Mesothelioma Malignant                    |          |             |                            |                            |                            |                            | X                          |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                  |                  |          |   | 1 |
| Neural Crest Tumor, Metastatic, Ear       |          |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            | X                          |                            |                            |                            |                            |                            |                            |                            |                  |                  |          |   | 1 |
| Osteosarcoma, Metastatic, Skin            |          |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            | X                          |                            |                            |                            |                            |                            |                            |                  |                  |          |   | 1 |
| Nose                                      |          |             | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                | +                | 50       |   |   |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

**Test Type: CHRONIC**

## **Route: GAVAGE**

**Species/Strain:** RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

## Kava kava extract

**CAS Number:** 9000-38-8

**Date Report Requested:** 09/21/2010

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**First Dose M/F:** 08/18/04 / 08/19/04

## Lab: BAT

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TDMS No. 20007 - 05

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## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

DAY ON TEST

**FISCHER 344 RATS MALE****0.3 G/KG**

ANIMAL ID

|                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |
|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| 0<br>7<br>2<br>9      | 0<br>7<br>6<br>7      | 0<br>6<br>3<br>0      | 0<br>7<br>2<br>8      | 0<br>7<br>2<br>7      | 0<br>7<br>2<br>8      | 0<br>7<br>2<br>9      | 0<br>7<br>2<br>8      | 0<br>7<br>2<br>8      | 0<br>7<br>2<br>8      | 0<br>7<br>2<br>1      | 0<br>7<br>2<br>8      | 0<br>7<br>2<br>7      | 0<br>6<br>2<br>9      | 0<br>7<br>2<br>8      | 0<br>7<br>2<br>9      | 0<br>7<br>2<br>7      | 0<br>7<br>2<br>8      | 0<br>7<br>2<br>8      | 0<br>7<br>2<br>8      |
| 0<br>0<br>1<br>0<br>1 | 0<br>0<br>1<br>1<br>1 |
| 0<br>2<br>3<br>4<br>5 | 0<br>1<br>2<br>3<br>4 |
| 1<br>0<br>1<br>0<br>1 | 1<br>1<br>2<br>3<br>4 |
| 6<br>6<br>7<br>6<br>7 | 6<br>6<br>7<br>6<br>7 | 7<br>7<br>8<br>7<br>8 |                       |

males  
(cont...)**ALIMENTARY SYSTEM**

Esophagus

Intestine Large, Cecum

Intestine Large, Colon

Intestine Large, Rectum

Intestine Small, Duodenum

Intestine Small, Ileum

Intestine Small, Jejunum

Liver

Fibrosarcoma, Metastatic, Stomach, Glandular

Leukemia Mononuclear

Mesentery

Leukemia Mononuclear

Lymphoma Malignant

Pancreas

Lymphoma Malignant

Acinus, Adenoma

Salivary Glands

Schwannoma Malignant

+ +

+ +

+ +

+ +

+ +

+ +

+ +

+ +

+ +

+ +

X X X X

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

**Test Type: CHRONIC**

## **Route: GAVAGE**

**Species/Strain:** RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

## Kava kava extract

CAS Number: 9000-38-8

**Date Report Requested:** 09/21/2010

**Time Report Requested:** 09:10:56

**First Dose M/F:** 08/18/04 / 08/19/04

## Lab: BAT

| FISCHER 344 RATS MALE | 0.3 G/KG | ANIMAL ID | DAY ON TEST |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | males<br>(cont...) |  |
|-----------------------|----------|-----------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------------|--|
|                       |          |           |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                    |  |
|                       |          |           | 7           | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |                    |  |
|                       |          |           | 2           | 2 | 6 | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2                  |  |
|                       |          |           | 9           | 7 | 4 | 0 | 8 | 7 | 8 | 9 | 9 | 8 | 8 | 8 | 1 | 8 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7                  |  |
|                       |          |           | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                  |  |
|                       |          |           | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                  |  |
|                       |          |           | 1           | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1                  |  |
|                       |          |           | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2                  |  |
|                       |          |           | 1           | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2                  |  |

## Stomach, Forestomach Lymphoma Malignant

Stomach, Glandular  
Carcinoid Tumor Malignant  
Lymphoma Malignant  
Muscularis, Fibrosarcoma

## Tooth

## CARDIOVASCULAR SYSTEM

## Blood Vessel

## Heart Lymphoma Malignant

## **ENDOCRINE SYSTEM**

## Adrenal Cortex Leukemia Mononuclear

Adrenal Medulla  
Leukemia Mononuclear  
Pheochromocytoma Benign

Islets, Pancreatic  
Adenoma  
Adenoma, Multiple

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

#### A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically



TDMS No. 20007 - 05

**Test Type: CHRONIC**

## **Route: GAVAGE**

**Species/Strain:** RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

## Kava kava extract

CAS Number: 9000-38-8

**Date Report Requested:** 09/21/2010

**Time Report Requested:** 09:10:56

**First Dose M/F:** 08/18/04 / 08/19/04

## Lab: BAT

## Lymphoma Malignant

Testes  
Bilateral, Interstitial Cell, Adenoma  
Interstitial Cell, Adenoma

## **HEMATOPOIETIC SYSTEM**

## Bone Marrow

### Lymph Node

## Lymph Node, Mandibular

Lymph Node, Mesenteric  
Leukemia Mononuclear  
Lymphoma Malignant

Spleen  
Leukemia Mononuclear

## Thymus Lymphoma Malignant

## **INTEGUMENTARY SYSTEM**

## Mammary Gland Fibroadenoma

## Skin Basal Cell Adenoma

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

### I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically





TDMS No. 20007 - 05

**Test Type: CHRONIC**

## **Route: GAVAGE**

**Species/Strain:** RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

## Kava kava extract

CAS Number: 9000-38-8

**Date Report Requested:** 09/21/2010

**Time Report Requested:** 09:10:56

**First Dose M/F:** 08/18/04 / 08/19/04

## Lab: BAT

| FISCHER 344 RATS MALE<br>0.3 G/KG | DAY ON TEST |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     | males<br>(cont...) |                    |
|-----------------------------------|-------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|--------------------|--------------------|
|                                   |             | 077 | 066 | 077 | 077 | 077 | 077 | 077 | 077 | 077 | 077 | 077 | 077 | 077 | 077 | 077 | 077 | 077 | 077 | 077 | 077 |                    |                    |
| ANIMAL ID                         | 097         | 074 | 060 | 087 | 028 | 078 | 098 | 099 | 089 | 088 | 018 | 028 | 018 | 028 | 072 | 027 | 029 | 082 | 028 | 029 | 072 | 028                | males<br>(cont...) |
|                                   | 000         | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000                |                    |
|                                   | 000         | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000                |                    |
|                                   | 111         | 111 | 111 | 111 | 111 | 111 | 111 | 111 | 111 | 111 | 111 | 111 | 111 | 111 | 111 | 111 | 111 | 111 | 111 | 111 | 111 | 111                |                    |
|                                   | 000         | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000                |                    |
|                                   | 12          | 3   | 4   | 5   | 6   | 7   | 8   | 9   | 0   | 1   | 2   | 3   | 4   | 5   | 6   | 7   | 8   | 9   | 0   | 1   | 2   | 3                  |                    |

## Mesothelioma Malignant

X

**males**  
**(cont...)**

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

#### A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

|                 |  | DAY ON TEST | 0<br>7<br>2<br>7      | 0<br>7<br>2<br>7      | 0<br>5<br>9<br>8      | 0<br>6<br>6<br>4      | 0<br>7<br>2<br>9      | 0<br>7<br>2<br>9      | 0<br>7<br>2<br>7      | 0<br>6<br>0<br>8      | 0<br>6<br>2<br>7      | 0<br>6<br>1<br>7      | 0<br>6<br>3<br>6      | 0<br>7<br>2<br>7      | 0<br>5<br>9<br>0      | 0<br>7<br>2<br>8      | 0<br>7<br>2<br>9      | 0<br>4<br>5<br>4      | 0<br>6<br>6<br>4      | 0<br>7<br>2<br>8      |                       |                       |
|-----------------|--|-------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
|                 |  | ANIMAL ID   | 0<br>0<br>1<br>2<br>6 | 0<br>0<br>1<br>2<br>7 | 0<br>0<br>1<br>2<br>8 | 0<br>0<br>1<br>3<br>9 | 0<br>0<br>1<br>3<br>0 | 0<br>0<br>1<br>3<br>1 | 0<br>0<br>1<br>3<br>4 | 0<br>0<br>1<br>3<br>5 | 0<br>0<br>1<br>3<br>6 | 0<br>0<br>1<br>3<br>7 | 0<br>0<br>1<br>3<br>8 | 0<br>0<br>1<br>3<br>9 | 0<br>0<br>1<br>4<br>0 | 0<br>0<br>1<br>4<br>1 | 0<br>0<br>1<br>4<br>2 | 0<br>0<br>1<br>4<br>3 | 0<br>0<br>1<br>4<br>4 | 0<br>0<br>1<br>4<br>5 | 0<br>0<br>1<br>4<br>6 | 0<br>0<br>1<br>4<br>7 |
| <b>* TOTALS</b> |  |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |

**ALIMENTARY SYSTEM**

|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Esophagus                                    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Cecum                       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Colon                       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Rectum                      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Duodenum                    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Ileum                       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Jejunum                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Liver  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Fibrosarcoma, Metastatic, Stomach, Glandular |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Leukemia Mononuclear                         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 7  |
| Mesentery                                    | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 7  |
| Leukemia Mononuclear                         |   | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Lymphoma Malignant                           |   |   | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Pancreas                                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Lymphoma Malignant                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Acinus, Adenoma                              |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Salivary Glands                              | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Schwannoma Malignant                         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2  |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

**Test Type: CHRONIC**

## **Route: GAVAGE**

**Species/Strain:** RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

## Kava kava extract

CAS Number: 9000-38-8

**Date Report Requested:** 09/21/2010

**Time Report Requested:** 09:10:56

**First Dose M/F:** 08/18/04 / 08/19/04

## Lab: BAT

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+ .. Tissue examined microscopically

X .. Lesion present

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TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

| FISCHER 344 RATS MALE      | 0.3 G/KG | DAY ON TEST | ANIMAL ID |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |   |    | * TOTALS |   |
|----------------------------|----------|-------------|-----------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|---|---|---|----|----------|---|
|                            |          |             |           | 0<br>7<br>2<br>7 | 0<br>7<br>2<br>7 | 0<br>7<br>2<br>8 | 0<br>5<br>9<br>8 | 0<br>6<br>6<br>4 | 0<br>7<br>9<br>4 | 0<br>7<br>2<br>8 | 0<br>7<br>2<br>9 | 0<br>6<br>8<br>9 | 0<br>6<br>0<br>8 | 0<br>7<br>2<br>7 | 0<br>6<br>1<br>7 | 0<br>6<br>7<br>3 | 0<br>7<br>2<br>7 | 0<br>5<br>9<br>0 | 0<br>7<br>2<br>8 | 0<br>7<br>2<br>9 | 0<br>4<br>5<br>4 | 0<br>6<br>6<br>4 | 0<br>7<br>2<br>8 |   |   |   |    |          |   |
| Parathyroid Gland          |          |             |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | M                | +                | +                | +                | + | + | + | +  | 48       |   |
| Pituitary Gland            |          |             |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | + | + | 50 |          |   |
| Pars Distalis, Adenoma     |          |             |           | X                |                  | X                | X                | X                |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  | X                |                  |                  |                  |   |   |   |    | 15       |   |
| Thyroid Gland              |          |             |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | + | + | 50 |          |   |
| Bilateral, C-cell, Adenoma |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |   |    | 2        |   |
| C-cell, Adenoma            |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |   |    | 6        |   |
| C-cell, Carcinoma          |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |   |    | 2        |   |
| Follicular Cell, Adenoma   |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |   |    | 1        |   |
| Follicular Cell, Carcinoma |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |   |    | 1        |   |
| <b>GENERAL BODY SYSTEM</b> |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |   |    |          |   |
| Peritoneum                 |          |             |           | +                |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |   |    |          | 1 |
| Paraganglioma              |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |   |    |          | 1 |
| <b>GENITAL SYSTEM</b>      |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |   |    |          |   |
| Epididymis                 |          |             |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | + | + | 50 |          |   |
| Lymphoma Malignant         |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |   |    |          | 1 |
| Mesothelioma Malignant     |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |   |    |          | 1 |
| Preputial Gland            |          |             |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | M                | +                | +                | +                | +                | +                | + | + | + | 49 |          |   |
| Lymphoma Malignant         |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |   |    |          | 1 |
| Prostate                   |          |             |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | + | + | 50 |          |   |
| Adenoma                    |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |   |    |          | 1 |
| Lymphoma Malignant         |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |   |    |          | 1 |
| Seminal Vesicle            |          |             |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | + | + | 50 |          |   |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

**Test Type: CHRONIC**

## **Route: GAVAGE**

**Species/Strain:** RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

### Kaya kaya extract

**CAS Number:** 9000-38-8

**Date Report Requested:** 09/21/2010

**Time Report Requested:** 09:10:56

**First Dose M/F:** 08/18/04 / 08/19/04

## Lab: BAT

## **INTEGUMENTARY SYSTEM**

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

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TDMS No. 20007 - 05

**Test Type: CHRONIC**

## **Route: GAVAGE**

**Species/Strain:** RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

## Kaya kaya extract

CAS Number: 9000-38-8

**Date Report Requested:** 09/21/2010

**Time Report Requested:** 09:10:56

**First Dose M/F:** 08/18/04 / 08/19/04

## Lab: BAT

## MUSCULOSKELETAL SYSTEM

## **NERVOUS SYSTEM**

## RESPIRATORY SYSTEM

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

#### I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

| FISCHER 344 RATS MALE                             | 0.3 G/KG | DAY ON TEST | ANIMAL ID |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |    | * TOTALS |   |
|---|----------|-------------|-----------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|---|---|----|----------|---|
|   |          |             |           | 0<br>7<br>2<br>7 | 0<br>7<br>2<br>7 | 0<br>7<br>2<br>8 | 0<br>5<br>9<br>8 | 0<br>6<br>6<br>4 | 0<br>7<br>9<br>9 | 0<br>7<br>2<br>8 | 0<br>6<br>8<br>9 | 0<br>7<br>2<br>7 | 0<br>6<br>1<br>7 | 0<br>6<br>3<br>6 | 0<br>7<br>2<br>7 | 0<br>5<br>9<br>0 | 0<br>7<br>2<br>8 | 0<br>7<br>2<br>9 | 0<br>4<br>5<br>4 | 0<br>6<br>6<br>4 | 0<br>7<br>2<br>8 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 |   |   |    |          |   |
| Schwannoma Malignant, Metastatic, Salivary Glands |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   | X  | 1        |   |
| Squamous Cell Carcinoma, Metastatic, Skin         |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |    | 1        |   |
| Nose  |          |             |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | + | 50 |          |   |
| Trachea   |          |             |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | + | 50 |          |   |
| <b>SPECIAL SENSES SYSTEM</b>                      |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |    |          |   |
| Ear   |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |    |          | 1 |
| Neural Crest Tumor                                |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |    |          | 1 |
| Eye   |          |             |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | + | 50 |          |   |
| Harderian Gland                                   |          |             |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | + | 50 |          |   |
| Zymbal's Gland                                    |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |    |          | 1 |
| Carcinoma   |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |    |          | 1 |
| <b>URINARY SYSTEM</b>                             |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |    |          |   |
| Kidney  |          |             |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | + | 50 |          |   |
| Urinary Bladder                                   |          |             |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | + | 50 |          |   |
| Lymphoma Malignant                                |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |    |          | 1 |
| <b>SYSTEMIC LESIONS</b>                           |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |    |          |   |
| Multiple Organ                                    |          |             |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | + | 50 |          |   |
| Leukemia Mononuclear                              |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |    |          | 7 |
| Lymphoma Malignant                                |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |   |    |          | 1 |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

|                       |          | DAY ON TEST | 0<br>7 | 0<br>7 | 0<br>7 | 0<br>5 | 0<br>6 | 0<br>7 | 0<br>6 | 0<br>7 | 0<br>7 | 0<br>6 | 0<br>6 | 0<br>7 | 0<br>6 | 0<br>7 | 0<br>7 | 0<br>5 | 0<br>7 | 0<br>7 | 0<br>4 | 0<br>6 | 0<br>7 |        |        |
|-----------------------|----------|-------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|
|                       |          | ANIMAL ID   | 2<br>7 | 2<br>7 | 2<br>7 | 2<br>8 | 9<br>8 | 6<br>4 | 0<br>9 | 9<br>4 | 2<br>8 | 2<br>9 | 2<br>7 | 2<br>9 | 0<br>8 | 2<br>7 | 1<br>6 | 7<br>3 | 2<br>7 | 2<br>9 | 9<br>0 | 2<br>8 | 5<br>4 | 6<br>4 | 2<br>8 |
| FISCHER 344 RATS MALE | 0.3 G/KG | 0<br>0      | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 | 0<br>0 |        |
|                       |          | 1<br>1      | 1<br>1 | 1<br>1 | 1<br>1 | 1<br>1 | 1<br>1 | 1<br>1 | 1<br>1 | 1<br>1 | 1<br>1 | 1<br>1 | 1<br>1 | 1<br>1 | 1<br>1 | 1<br>1 | 1<br>1 | 1<br>1 | 1<br>1 | 1<br>1 | 1<br>1 | 1<br>1 | 1<br>1 | 1<br>1 |        |
|                       |          | 2<br>6      | 2<br>7 | 2<br>8 | 2<br>9 | 2<br>0 | 2<br>1 | 2<br>2 | 3<br>2 | 3<br>3 | 4<br>0 | 4<br>1 | 4<br>2 | 4<br>3 | 4<br>4 |
|                       |          |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |

\* TOTALS

Mesothelioma Malignant

1

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

DAY ON TEST

**FISCHER 344 RATS MALE****1.0 G/KG**

ANIMAL ID

|                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                  |
|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|------------------|
| 0<br>7<br>2<br>7      | 0<br>7<br>5<br>2<br>7 | 0<br>5<br>5<br>8<br>2 | 0<br>7<br>2<br>2<br>9 | 0<br>7<br>4<br>0<br>7 | 0<br>6<br>7<br>2<br>3 | 0<br>7<br>6<br>2<br>8 | 0<br>7<br>6<br>2<br>0 | 0<br>7<br>6<br>2<br>9 | 0<br>7<br>7<br>2<br>9 | 0<br>6<br>6<br>2<br>7 | 0<br>7<br>7<br>2<br>7 | 0<br>6<br>6<br>2<br>7 | 0<br>7<br>7<br>2<br>7 | 0<br>6<br>6<br>2<br>7 | 0<br>7<br>7<br>2<br>7 | 0<br>6<br>7<br>2<br>8 | 0<br>7<br>7<br>2<br>8 |                  |
| 0<br>0<br>1<br>5<br>1 |                  |
| 1<br>5<br>1<br>2      | 1<br>5<br>5<br>2      | 1<br>5<br>5<br>3      | 1<br>5<br>5<br>4      | 1<br>5<br>5<br>5      | 1<br>5<br>5<br>6      | 1<br>5<br>5<br>7      | 1<br>5<br>5<br>8      | 1<br>5<br>5<br>9      | 1<br>5<br>6<br>0      | 1<br>5<br>6<br>1      | 1<br>5<br>6<br>2      | 1<br>5<br>6<br>3      | 1<br>5<br>6<br>4      | 1<br>5<br>6<br>5      | 1<br>5<br>6<br>6      | 1<br>5<br>6<br>7      | 1<br>5<br>6<br>8      | 1<br>5<br>6<br>9 |
| 2<br>3<br>4<br>5<br>6 |                  |

males  
(cont...)**ALIMENTARY SYSTEM**

Esophagus

+ +

Intestine Large, Cecum

+ +

Intestine Large, Colon

+ +

Intestine Large, Rectum

+ +

Intestine Small, Duodenum

+ +

Intestine Small, Ileum

+ +

Intestine Small, Jejunum

+ +

Liver

+ +

Fibrous Histiocytoma, Metastatic, Skeletal Muscle

X

Hepatocellular Adenoma

X

Leukemia Mononuclear

X X X

Mesentery

+

Mesothelioma Malignant

X

Oral Mucosa

+

Squamous Cell Carcinoma

X

Pancreas

+ +

Salivary Glands

+ +

\* .. Total animals with tissue examined microscopically; Total animals with tumor

M .. Missing tissue

+ .. Tissue examined microscopically

A .. Autolysis precludes evaluation

X .. Lesion present

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I .. Insufficient tissue

TDMS No. 20007 - 05

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Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

|   |  | DAY ON TEST | 0<br>7<br>2<br>7      | 0<br>7<br>2<br>7      | 0<br>5<br>5<br>6      | 0<br>8<br>2<br>9      | 0<br>2<br>2<br>9      | 0<br>7<br>0<br>9      | 0<br>4<br>4<br>7      | 0<br>6<br>7<br>3      | 0<br>7<br>2<br>8      | 0<br>6<br>4<br>0      | 0<br>7<br>2<br>9      | 0<br>7<br>2<br>9      | 0<br>6<br>2<br>7      | 0<br>7<br>2<br>7      | 0<br>6<br>2<br>7      | 0<br>7<br>2<br>7      | 0<br>6<br>2<br>7      | 0<br>7<br>2<br>8      |                       |                       |                       |                       |                       |                       |                    |
|---|--|-------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|--------------------|
|   |  | ANIMAL ID   | 0<br>0<br>1<br>5<br>1 | 0<br>0<br>1<br>5<br>2 | 0<br>0<br>1<br>5<br>3 | 0<br>0<br>1<br>5<br>4 | 0<br>0<br>1<br>5<br>5 | 0<br>0<br>1<br>5<br>6 | 0<br>0<br>1<br>5<br>7 | 0<br>0<br>1<br>5<br>8 | 0<br>0<br>1<br>5<br>9 | 0<br>0<br>1<br>6<br>0 | 0<br>0<br>1<br>6<br>1 | 0<br>0<br>1<br>6<br>2 | 0<br>0<br>1<br>6<br>3 | 0<br>0<br>1<br>6<br>4 | 0<br>0<br>1<br>6<br>5 | 0<br>0<br>1<br>6<br>6 | 0<br>0<br>1<br>6<br>7 | 0<br>0<br>1<br>6<br>8 | 0<br>0<br>1<br>6<br>9 | 0<br>0<br>1<br>7<br>0 | 0<br>0<br>1<br>7<br>1 | 0<br>0<br>1<br>7<br>2 | 0<br>0<br>1<br>7<br>3 | 0<br>0<br>1<br>7<br>4 | males<br>(cont...) |
| <b>FISCHER 344 RATS MALE</b>                      |  |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                    |
| <b>1.0 G/KG</b>                                   |  |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                    |
| Sarcoma   |  |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                    |
| Stomach, Forestomach                              |  |             | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     |                    |
| Mesothelioma Malignant                            |  |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                    |
| X   |  |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                    |
| Stomach, Glandular                                |  |             | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     |                    |
| Tooth   |  |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                    |
|   |  |             | +                     |                       | +                     |                       | +                     |                       | +                     |                       | +                     |                       | +                     |                       | +                     |                       | +                     |                       | +                     |                       | +                     |                       | +                     |                       | +                     |                       |                    |
| <b>CARDIOVASCULAR SYSTEM</b>                      |  |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                    |
| Blood Vessel                                      |  |             | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     |                    |
| Heart   |  |             | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     |                    |
| Fibrous Histiocytoma, Metastatic, Skeletal Muscle |  |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                    |
| Leukemia Mononuclear                              |  |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                    |
| X   |  |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                    |
| <b>ENDOCRINE SYSTEM</b>                           |  |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                    |
| Adrenal Cortex                                    |  |             | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     |                    |
| Leukemia Mononuclear                              |  |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                    |
| X   |  |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                    |
| Adrenal Medulla                                   |  |             | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     |                    |
| Leukemia Mononuclear                              |  |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                    |
| Pheochromocytoma Benign                           |  |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                    |
| X   |  |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                    |
| Islets, Pancreatic Adenoma                        |  |             | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     |                    |
| X   |  |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                    |
| Parathyroid Gland                                 |  |             | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     |                    |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically



TDMS No. 20007 - 05

**Test Type: CHRONIC**

## **Route: GAVAGE**

**Species/Strain:** RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

## Kava kava extract

CAS Number: 9000-38-8

**Date Report Requested:** 09/21/2010

**Time Report Requested:** 09:10:56

**First Dose M/F:** 08/18/04 / 08/19/04

## Lab: BAT

## **INTEGUMENTARY SYSTEM**

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

#### I .. Insufficient tissue

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TDMS No. 20007 - 05

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Lab: BAT

|                       |          | DAY ON TEST | 0<br>7<br>2<br>7      | 0<br>7<br>2<br>7      | 0<br>5<br>5<br>6      | 0<br>8<br>2<br>9      | 0<br>2<br>2<br>9      | 0<br>2<br>2<br>7      | 0<br>7<br>9           | 0<br>4<br>7           | 0<br>6<br>3           | 0<br>7<br>8           | 0<br>6<br>0           | 0<br>7<br>9           | 0<br>7<br>2           | 0<br>6<br>5           | 0<br>7<br>7           | 0<br>7<br>2           | 0<br>6<br>7           | 0<br>7<br>7           | 0<br>7<br>0           | 0<br>7<br>2           | 0<br>7<br>8           |                       |                       |                    |
|-----------------------|----------|-------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|--------------------|
|                       |          | ANIMAL ID   | 0<br>0<br>1<br>5<br>1 | 0<br>0<br>1<br>5<br>2 | 0<br>0<br>1<br>5<br>3 | 0<br>0<br>1<br>5<br>4 | 0<br>0<br>1<br>5<br>5 | 0<br>0<br>1<br>5<br>6 | 0<br>0<br>1<br>5<br>7 | 0<br>0<br>1<br>5<br>8 | 0<br>0<br>1<br>5<br>9 | 0<br>0<br>1<br>6<br>0 | 0<br>0<br>1<br>6<br>1 | 0<br>0<br>1<br>6<br>2 | 0<br>0<br>1<br>6<br>3 | 0<br>0<br>1<br>6<br>4 | 0<br>0<br>1<br>6<br>5 | 0<br>0<br>1<br>6<br>6 | 0<br>0<br>1<br>6<br>7 | 0<br>0<br>1<br>6<br>8 | 0<br>0<br>1<br>6<br>9 | 0<br>0<br>1<br>7<br>0 | 0<br>0<br>1<br>7<br>1 | 0<br>0<br>1<br>7<br>2 | 0<br>0<br>1<br>7<br>3 | males<br>(cont...) |
| FISCHER 344 RATS MALE | 1.0 G/KG |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                    |

Dermis, Fibroma

X

Subcutaneous Tissue, Fibroma

## MUSCULOSKELETAL SYSTEM

Bone

+ +

Skeletal Muscle  
Fibrous Histiocytoma+  
X

## NERVOUS SYSTEM

Brain

+ +

## RESPIRATORY SYSTEM

Lung

+ +

Alveolar/Bronchiolar Adenoma

X

Fibrous Histiocytoma, Metastatic, Skeletal  
Muscle

X

Leukemia Mononuclear

X

X X X

Nose

+ +

Trachea

+ +

## SPECIAL SENSES SYSTEM

Eye

+ +

Harderian Gland

+ +

\* .. Total animals with tissue examined microscopically; Total animals with tumor

M .. Missing tissue

+ .. Tissue examined microscopically

A .. Autolysis precludes evaluation

X .. Lesion present

BLANK .. Not examined microscopically

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TDMS No. 20007 - 05

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Kava kava extract

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First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

|                       | DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|-----------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                       |             | 7 | 7 | 5 | 5 | 7 | 7 | 6 | 7 | 7 | 4 | 6 | 7 | 6 | 7 | 7 | 0 | 7 | 6 | 6 | 7 | 6 | 7 | 0 | 7 | 7 | 0 |
| FISCHER 344 RATS MALE | 1.0 G/KG    | 2 | 2 | 5 | 8 | 2 | 2 | 2 | 2 | 0 | 4 | 7 | 2 | 4 | 2 | 2 | 9 | 2 | 9 | 6 | 6 | 2 | 7 | 7 | 2 | 3 | 2 |
|                       |             | 7 | 7 | 6 | 9 | 8 | 9 | 9 | 7 | 9 | 7 | 3 | 8 | 0 | 9 | 9 | 7 | 4 | 5 | 7 | 7 | 7 | 9 | 7 | 7 | 0 | 2 |
|                       | ANIMAL ID   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                       |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                       |             | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
|                       |             | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 |
|                       |             | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 5 |

males  
(cont...)

Carcinoma, Metastatic, Oral Mucosa

X

## URINARY SYSTEM

Kidney  
Leukemia Mononuclear

+ +

X

Urinary Bladder

+ +

## SYSTEMIC LESIONS

Multiple Organ  
Leukemia Mononuclear  
Lymphoma Malignant  
Mesothelioma Malignant

+ +

X

X

X

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

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Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

|                       |          | DAY ON TEST | 0<br>7<br>2<br>9      | 0<br>7<br>2<br>9      | 0<br>7<br>2<br>8      | 0<br>7<br>2<br>7      | 0<br>6<br>8<br>9      | 0<br>5<br>2<br>8      | 0<br>6<br>3<br>0      | 0<br>4<br>7<br>4      | 0<br>7<br>2<br>1      | 0<br>4<br>2<br>7      | 0<br>7<br>2<br>9      | 0<br>7<br>2<br>9      | 0<br>7<br>2<br>3      | 0<br>7<br>2<br>8      | 0<br>7<br>2<br>7      | 0<br>7<br>2<br>8      | 0<br>7<br>2<br>9      | 0<br>5<br>2<br>9      | 0<br>7                |                       |                       |          |
|-----------------------|----------|-------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|----------|
|                       |          | ANIMAL ID   | 0<br>0<br>1<br>7<br>6 | 0<br>0<br>1<br>7<br>7 | 0<br>0<br>1<br>8<br>9 | 0<br>0<br>1<br>8<br>0 | 0<br>0<br>1<br>8<br>1 | 0<br>0<br>1<br>8<br>2 | 0<br>0<br>1<br>8<br>3 | 0<br>0<br>1<br>8<br>4 | 0<br>0<br>1<br>8<br>5 | 0<br>0<br>1<br>8<br>6 | 0<br>0<br>1<br>8<br>7 | 0<br>0<br>1<br>8<br>8 | 0<br>0<br>1<br>8<br>9 | 0<br>0<br>1<br>9<br>0 | 0<br>0<br>1<br>9<br>1 | 0<br>0<br>1<br>9<br>2 | 0<br>0<br>1<br>9<br>3 | 0<br>0<br>1<br>9<br>4 | 0<br>0<br>1<br>9<br>5 | 0<br>0<br>1<br>9<br>6 | 0<br>0<br>1<br>9<br>7 | * TOTALS |
| FISCHER 344 RATS MALE | 1.0 G/KG |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |          |

## ALIMENTARY SYSTEM

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Esophagus   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Cecum                            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Colon                            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Rectum                           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Duodenum                         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Ileum                            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Jejunum                          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Liver   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Fibrous Histiocytoma, Metastatic, Skeletal Muscle |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Hepatocellular Adenoma                            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Leukemia Mononuclear                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 9  |
| Mesentery   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 6  |
| Mesothelioma Malignant                            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Oral Mucosa                                       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Squamous Cell Carcinoma                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Pancreas  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Salivary Glands                                   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

|   |          | DAY ON TEST | 0<br>7<br>2<br>9      | 0<br>7<br>2<br>9      | 0<br>7<br>2<br>8      | 0<br>7<br>2<br>7      | 0<br>6<br>2<br>9      | 0<br>5<br>8           | 0<br>6<br>3           | 0<br>6<br>0           | 0<br>4<br>4           | 0<br>7<br>2           | 0<br>4<br>1           | 0<br>7<br>7           | 0<br>7<br>2           | 0<br>7<br>3           | 0<br>7<br>2           | 0<br>7<br>8           | 0<br>7<br>2           | 0<br>7<br>2           | 0<br>7<br>8           | 0<br>7<br>2           | 0<br>5<br>9           | 0<br>7                |                       |          |    |
|---|----------|-------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|----------|----|
|   |          | ANIMAL ID   | 0<br>0<br>1<br>7<br>6 | 0<br>0<br>1<br>7<br>7 | 0<br>0<br>1<br>8<br>9 | 0<br>0<br>1<br>8<br>0 | 0<br>0<br>1<br>8<br>1 | 0<br>0<br>1<br>8<br>2 | 0<br>0<br>1<br>8<br>3 | 0<br>0<br>1<br>8<br>4 | 0<br>0<br>1<br>8<br>5 | 0<br>0<br>1<br>8<br>6 | 0<br>0<br>1<br>8<br>7 | 0<br>0<br>1<br>8<br>8 | 0<br>0<br>1<br>8<br>9 | 0<br>0<br>1<br>9<br>0 | 0<br>0<br>1<br>9<br>1 | 0<br>0<br>1<br>9<br>2 | 0<br>0<br>1<br>9<br>3 | 0<br>0<br>1<br>9<br>4 | 0<br>0<br>1<br>9<br>5 | 0<br>0<br>1<br>9<br>6 | 0<br>0<br>1<br>9<br>7 | 0<br>0<br>1<br>9<br>8 | 0<br>0<br>1<br>9<br>9 | * TOTALS |    |
| FISCHER 344 RATS MALE                             | 1.0 G/KG |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |          |    |
| Sarcoma   |          |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       | X        | 1  |
| Stomach, Forestomach                              |          |             | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | 50       |    |
| Mesothelioma Malignant                            |          |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |          | 1  |
| Stomach, Glandular                                |          |             | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | 50       |    |
| Tooth   |          |             | +                     | +                     | +                     |                       |                       | +                     |                       | +                     |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       | +        | 11 |
| <b>CARDIOVASCULAR SYSTEM</b>                      |          |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |          |    |
| Blood Vessel                                      |          |             | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | 50       |    |
| Heart   |          |             | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | 50       |    |
| Fibrous Histiocytoma, Metastatic, Skeletal Muscle |          |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |          | 1  |
| Leukemia Mononuclear                              |          |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |          | 2  |
| <b>ENDOCRINE SYSTEM</b>                           |          |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |          |    |
| Adrenal Cortex                                    |          |             | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | 50       |    |
| Leukemia Mononuclear                              |          |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |          | 5  |
| Adrenal Medulla                                   |          |             | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | 50       |    |
| Leukemia Mononuclear                              |          |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |          | 3  |
| Pheochromocytoma Benign                           |          |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |          | 2  |
| Islets, Pancreatic                                |          |             | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | 50       |    |
| Adenoma   |          |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |          | 3  |
| Parathyroid Gland                                 |          |             | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | 50       |    |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

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TDMS No. 20007 - 05

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Kava kava extract

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Lab: BAT

|   |          | DAY ON TEST | 0<br>7<br>2<br>9      | 0<br>7<br>2<br>9      | 0<br>7<br>2<br>8      | 0<br>6<br>2<br>8      | 0<br>5<br>8           | 0<br>6<br>3           | 0<br>6<br>0           | 0<br>4<br>4           | 0<br>7<br>2           | 0<br>4<br>1           | 0<br>7<br>7           | 0<br>7<br>2           | 0<br>7<br>3           | 0<br>7<br>2           | 0<br>7<br>8           | 0<br>7<br>2           | 0<br>7<br>7           | 0<br>7<br>2           | 0<br>5<br>9           | 0<br>7                |                       |                       |                       |          |
|---|----------|-------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|----------|
|   |          | ANIMAL ID   | 0<br>0<br>1<br>7<br>6 | 0<br>0<br>1<br>7<br>7 | 0<br>0<br>1<br>8<br>9 | 0<br>0<br>1<br>8<br>0 | 0<br>0<br>1<br>8<br>1 | 0<br>0<br>1<br>8<br>2 | 0<br>0<br>1<br>8<br>3 | 0<br>0<br>1<br>8<br>4 | 0<br>0<br>1<br>8<br>5 | 0<br>0<br>1<br>8<br>6 | 0<br>0<br>1<br>8<br>7 | 0<br>0<br>1<br>8<br>8 | 0<br>0<br>1<br>8<br>9 | 0<br>0<br>1<br>9<br>0 | 0<br>0<br>1<br>9<br>1 | 0<br>0<br>1<br>9<br>2 | 0<br>0<br>1<br>9<br>3 | 0<br>0<br>1<br>9<br>4 | 0<br>0<br>1<br>9<br>5 | 0<br>0<br>1<br>9<br>6 | 0<br>0<br>1<br>9<br>7 | 0<br>0<br>1<br>9<br>8 | 0<br>0<br>1<br>9<br>9 | * TOTALS |
| FISCHER 344 RATS MALE                     | 1.0 G/KG |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |          |
| Pituitary Gland<br>Pars Distalis, Adenoma |          |             | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | 50<br>8               |          |
| Thyroid Gland<br>C-cell, Adenoma          |          |             | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | +                     | 50<br>2               |          |

## GENERAL BODY SYSTEM

NONE

## GENITAL SYSTEM

Epididymis  
Mesothelioma MalignantPreputial Gland  
AdenomaProstate  
Lymphoma Malignant

Seminal Vesicle

Testes  
Mesothelioma Malignant  
Bilateral, Interstitial Cell, Adenoma  
Interstitial Cell, Adenoma

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |         |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---------|
| + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50<br>3 |
| + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50<br>1 |
| + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50<br>1 |
| + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50<br>1 |
| + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 43<br>3 |

## HEMATOPOIETIC SYSTEM

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

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Species/Strain: RATS/F 344/N

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Kava kava extract

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First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

| FISCHER 344 RATS MALE   | 1.0 G/KG | DAY ON TEST | ANIMAL ID | * TOTALS |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |    |
|---|----------|-------------|-----------|----------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----|
|   |          |             |           | 0729     | 0729 | 0728 | 0727 | 0727 | 0629 | 0528 | 0629 | 0427 | 0428 | 0721 | 0727 | 0729 | 0729 | 0723 | 0728 | 0727 | 0728 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 |    |
| Bone Marrow   |          |             |           | +        | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 50   |    |
| Lymph Node  |          |             |           |          |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | 5  |
| Deep Cervical, Fibrous Histiocytoma,<br>Metastatic, Skeletal Muscle |          |             |           |          |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | 1  |
| Mediastinal, Leukemia Mononuclear                                   |          |             |           |          |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | 1  |
| Pancreatic, Leukemia Mononuclear                                    |          |             |           |          |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | 2  |
| Lymph Node, Mandibular  |          |             |           | M        | M    | M    | M    | M    | M    | M    | M    | M    | M    | M    | M    | M    | M    | M    | M    | M    | M    | M    | M    | M    | M    | M    | 0    |    |
| Lymph Node, Mesenteric  |          |             |           | +        | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 50   |    |
| Fibrous Histiocytoma, Metastatic, Skeletal<br>Muscle                |          |             |           |          |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | 1  |
| Leukemia Mononuclear  |          |             |           |          |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | 3  |
| Spleen  |          |             |           | +        | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 50   |    |
| Leukemia Mononuclear  |          |             |           |          |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | 11 |
| Lymphoma Malignant  |          |             |           |          |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | 1  |
| Thymus  |          |             |           | +        | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 50   |    |
| Fibrous Histiocytoma, Metastatic, Skeletal<br>Muscle                |          |             |           |          |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | 1  |
| Lymphoma Malignant  |          |             |           |          |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | 1  |
| <b>INTEGUMENTARY SYSTEM</b>   |          |             |           |          |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |    |
| Mammary Gland   |          |             |           | +        | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 50   |    |
| Fibroadenoma  |          |             |           |          |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | 3  |
| Skin  |          |             |           | +        | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | 50   |    |
| Basal Cell Adenoma  |          |             |           |          |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      | 1  |

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+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

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## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

|                              |          | DAY ON TEST | 0<br>7<br>2<br>9      | 0<br>7<br>2<br>9      | 0<br>7<br>2<br>8      | 0<br>6<br>9           | 0<br>5<br>8           | 0<br>6<br>3           | 0<br>6<br>0           | 0<br>4<br>4           | 0<br>7<br>2           | 0<br>4<br>1           | 0<br>7<br>7           | 0<br>7<br>2           | 0<br>7<br>3           | 0<br>7<br>8           | 0<br>7<br>2           | 0<br>7<br>7           | 0<br>7<br>2           | 0<br>7<br>9           | 0<br>5<br>9           | 0<br>7                |                       |                       |                       |                  |          |
|------------------------------|----------|-------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|------------------|----------|
|                              |          | ANIMAL ID   | 0<br>0<br>1<br>7<br>6 | 0<br>0<br>1<br>7<br>7 | 0<br>0<br>1<br>8<br>9 | 0<br>0<br>1<br>8<br>0 | 0<br>0<br>1<br>8<br>1 | 0<br>0<br>1<br>8<br>2 | 0<br>0<br>1<br>8<br>3 | 0<br>0<br>1<br>8<br>4 | 0<br>0<br>1<br>8<br>5 | 0<br>0<br>1<br>8<br>6 | 0<br>0<br>1<br>8<br>7 | 0<br>0<br>1<br>8<br>8 | 0<br>0<br>1<br>8<br>9 | 0<br>0<br>1<br>9<br>0 | 0<br>0<br>1<br>9<br>1 | 0<br>0<br>1<br>9<br>2 | 0<br>0<br>1<br>9<br>3 | 0<br>0<br>1<br>9<br>4 | 0<br>0<br>1<br>9<br>5 | 0<br>0<br>1<br>9<br>6 | 0<br>0<br>1<br>9<br>7 | 0<br>0<br>1<br>9<br>8 | 0<br>0<br>1<br>9<br>9 | 0<br>0<br>1<br>0 | * TOTALS |
| FISCHER 344 RATS MALE        | 1.0 G/KG |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                  |          |
| Dermis, Fibroma              |          |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                  | 1        |
| Subcutaneous Tissue, Fibroma |          |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                  | 1        |

## MUSCULOSKELETAL SYSTEM

|                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |   |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|---|
| Bone                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |
| Skeletal Muscle      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 |
| Fibrous Histiocytoma |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 |

## NERVOUS SYSTEM

|       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|-------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Brain | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
|-------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|

## RESPIRATORY SYSTEM

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|---|
| Lung  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |
| Alveolar/Bronchiolar Adenoma                      | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 4 |
| Fibrous Histiocytoma, Metastatic, Skeletal Muscle |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 |
| Leukemia Mononuclear                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 8 |
| Nose  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |
| Trachea   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |

## SPECIAL SENSES SYSTEM

|                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Eye             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Harderian Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

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Kava kava extract

CAS Number: 9000-38-8

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First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

|                                    |  | DAY ON TEST | 0<br>7<br>2<br>9      | 0<br>7<br>2<br>9      | 0<br>7<br>2<br>8      | 0<br>7<br>2<br>7      | 0<br>6<br>8<br>9      | 0<br>5<br>2<br>8      | 0<br>6<br>7<br>3      | 0<br>4<br>5<br>4      | 0<br>7<br>2<br>8      | 0<br>4<br>2<br>1      | 0<br>7<br>2<br>9      | 0<br>7<br>2<br>9      | 0<br>7<br>2<br>3      | 0<br>7<br>2<br>8      | 0<br>7<br>2<br>7      | 0<br>7<br>2<br>8      | 0<br>7<br>2<br>9      | 0<br>5<br>5<br>9      | 0<br>7<br>5<br>9      |                       |                       |                       |                       |          |
|------------------------------------|--|-------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|----------|
|                                    |  | ANIMAL ID   | 0<br>0<br>1<br>7<br>6 | 0<br>0<br>1<br>7<br>7 | 0<br>0<br>1<br>8<br>9 | 0<br>0<br>1<br>8<br>0 | 0<br>0<br>1<br>8<br>1 | 0<br>0<br>1<br>8<br>2 | 0<br>0<br>1<br>8<br>3 | 0<br>0<br>1<br>8<br>4 | 0<br>0<br>1<br>8<br>5 | 0<br>0<br>1<br>8<br>6 | 0<br>0<br>1<br>8<br>7 | 0<br>0<br>1<br>8<br>8 | 0<br>0<br>1<br>8<br>9 | 0<br>0<br>1<br>9<br>0 | 0<br>0<br>1<br>9<br>1 | 0<br>0<br>1<br>9<br>2 | 0<br>0<br>1<br>9<br>3 | 0<br>0<br>1<br>9<br>4 | 0<br>0<br>1<br>9<br>5 | 0<br>0<br>1<br>9<br>6 | 0<br>0<br>1<br>9<br>7 | 0<br>0<br>1<br>9<br>8 | 0<br>0<br>1<br>9<br>9 | * TOTALS |
| <b>FISCHER 344 RATS MALE</b>       |  |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |          |
| <b>1.0 G/KG</b>                    |  |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |          |
| Carcinoma, Metastatic, Oral Mucosa |  |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |          |
| URINARY SYSTEM                     |  |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |          |
| Kidney                             |  |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |          |
| Leukemia Mononuclear               |  |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |          |
| Urinary Bladder                    |  |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |          |
| SYSTEMIC LESIONS                   |  |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |          |
| Multiple Organ                     |  |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |          |
| Leukemia Mononuclear               |  |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |          |
| Lymphoma Malignant                 |  |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |          |
| Mesothelioma Malignant             |  |             |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |          |

\*\*\* END OF MALE DATA \*\*\*

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

**Test Type: CHRONIC**

## **Route: GAVAGE**

**Species/Strain:** RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

#### Kava kava extract

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**Date Report Requested:** 09/21/2010

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## Lab: BAT

# ALIMENTARY SYSTEM

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X., Lesion present

#### I. Insufficient tissue

M .. Missing tissue

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TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

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Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

| FISCHER 344 RATS FEMALE | 0.0 G/KG | DAY ON TEST |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    | females<br>(cont...) |
|-------------------------|----------|-------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----------------------|
|                         |          |             | 07 | 07 | 07 | 07 | 07 | 07 | 05 | 07 | 07 | 07 | 07 | 06 | 07 | 07 | 07 | 07 | 07 | 05 | 07 | 07 | 07 | 07 | 07 | 07 | 07 |                      |
| ANIMAL ID               | 05       | 08          | 02 | 03 | 02 | 02 | 03 | 02 | 03 | 03 | 02 | 02 | 03 | 02 | 02 | 02 | 02 | 02 | 02 | 01 | 08 | 02 | 09 | 02 | 08 | 02 | 08 | 02                   |
| Lymph Node, Mesenteric  | +        | +           | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  |                      |
| Leukemia Mononuclear    |          |             |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    | X  |    |    |    |    |    |    |    |                      |
| Lymphoma Malignant      |          |             |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |                      |
| Spleen                  | +        | +           | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  |                      |
| Leukemia Mononuclear    |          |             |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    | X  |    |    |    |    |    |    |    |                      |
| Lymphoma Malignant      |          |             |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    | X  |    |    |    |    |    |    |                      |
| Thymus                  | +        | +           | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  |                      |
| Lymphoma Malignant      |          |             |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |                      |

## INTEGUMENTARY SYSTEM

|                              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Mammary Gland                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
| Adenolipoma                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Adenoma                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Carcinoma                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Fibroadenoma                 | X | X | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Fibroadenoma, Multiple       |   |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X | X |   |   |   |   |   |   |   |  |
| Skin                         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
| Subcutaneous Tissue, Fibroma | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |

## MUSCULOSKELETAL SYSTEM

|                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Bone            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |  |
| Skeletal Muscle |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |

## NERVOUS SYSTEM

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

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TDMS No. 20007 - 05

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Route: GAVAGE

Species/Strain: RATS/F 344/N

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First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

| FISCHER 344 RATS FEMALE      | 0.0 G/KG | ANIMAL ID | DAY ON TEST |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    | females<br>(cont...) |   |  |
|------------------------------|----------|-----------|-------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----------------------|---|--|
|                              |          |           | 07          | 07 | 07 | 07 | 07 | 07 | 05 | 07 | 07 | 07 | 06 | 07 | 07 | 07 | 07 | 05 | 07 | 07 | 07 | 07 |                      |   |  |
|                              |          |           | 05          | 8  | 0  | 9  | 9  | 9  | 0  | 6  | 0  | 0  | 2  | 1  | 0  | 9  | 5  | 1  | 0  | 8  | 9  | 9  | 8                    |   |  |
|                              |          |           | 00          | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00                   |   |  |
|                              |          |           | 22          | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22                   |   |  |
|                              |          |           | 00          | 00 | 00 | 00 | 00 | 00 | 01 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11                   |   |  |
|                              |          |           | 11          | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 10 | 11                   |   |  |
| Brain                        |          |           | +           | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +                    |   |  |
| <b>RESPIRATORY SYSTEM</b>    |          |           |             |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |                      |   |  |
| Lung                         |          |           | +           | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +                    | + |  |
| Leukemia Mononuclear         |          |           |             |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |                      |   |  |
| Lymphoma Malignant           |          |           |             |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |                      |   |  |
| Mediastinum, Fibrosarcoma    |          |           |             |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |                      |   |  |
| Nose                         |          |           | +           | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +                    | + |  |
| Trachea                      |          |           | +           | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +                    | + |  |
| <b>SPECIAL SENSES SYSTEM</b> |          |           |             |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |                      |   |  |
| Ear                          |          |           |             |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |                      |   |  |
| Neural Crest Tumor           |          |           |             |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |                      |   |  |
| Eye                          |          |           | +           | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +                    | + |  |
| Harderian Gland              |          |           | +           | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +                    | + |  |
| <b>URINARY SYSTEM</b>        |          |           |             |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |                      |   |  |
| Kidney                       |          |           | +           | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +                    | + |  |
| Leukemia Mononuclear         |          |           |             |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |                      |   |  |
| Urinary Bladder              |          |           | +           | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +  | +                    | + |  |
| <b>SYSTEMIC LESIONS</b>      |          |           |             |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |                      |   |  |

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**Species/Strain:** RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

### Kaya kaya extract

CAS Number: 9000-38-8

**Date Report Requested:** 09/21/2010

**Time Report Requested:** 09:10:56

**First Dose M/F:** 08/18/04 / 08/19/04

## Lab: BAT

## Multiple Organ

### **Adenolipoma**

## Leukemia Mononuclear

## Lymphoma Malignant

x

x

X

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

### I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

| FISCHER 344 RATS FEMALE | DAY ON TEST |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |          |
|-------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|----------|
|                         |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          |          |
| 0.0 G/KG                | ANIMAL ID   | 6 | 4 | 7 | 7 | 7 | 7 | 7 | 5 | 6 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 6 | 6 | 7 | 6 | 7 | 7 | 2 | 2 | * TOTALS |          |
|                         |             | 9 | 5 | 0 | 3 | 2 | 3 | 2 | 2 | 1 | 6 | 1 | 2 | 2 | 3 | 9 | 3 | 2 | 9 | 3 | 2 | 9 | 3 | 2 | 9 | 2        |          |
| 0.0 G/KG                | ANIMAL ID   | 2 | 0 | 1 | 0 | 9 | 0 | 9 | 9 | 9 | 9 | 5 | 9 | 9 | 9 | 9 | 0 | 3 | 0 | 8 | 3 | 4 | 9 | 7 | 8 | 2        | * TOTALS |
|                         |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |          |
| 0.0 G/KG                | ANIMAL ID   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        | * TOTALS |
|                         |             | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2        |          |
| 0.0 G/KG                | ANIMAL ID   | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4        | * TOTALS |
|                         |             | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0        |          |

## ALIMENTARY SYSTEM

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |    |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|----|
| Esophagus                               | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |    |
| Intestine Large, Cecum                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |    |
| Intestine Large, Colon                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |    |
| Intestine Large, Rectum                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |    |
| Intestine Small, Duodenum               | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |    |
| Intestine Small, Ileum                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |    |
| Intestine Small, Jejunum                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |    |
| Liver                                   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |    |
| Leukemia Mononuclear                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 4  |
| Lymphoma Malignant                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1  |
| Mesentery                               | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 10 |
| Pancreas                                | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |    |
| Leukemia Mononuclear                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1  |
| Salivary Glands                         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |    |
| Stomach, Forestomach                    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |    |
| Sarcoma, Metastatic, Stomach, Glandular |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1  |
| Stomach, Glandular                      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |    |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

| FISCHER 344 RATS FEMALE        | DAY ON TEST |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |   |  |
|--------------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|---|--|
|                                |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          |   |  |
| 0.0 G/KG                       | ANIMAL ID   | 6 | 4 | 7 | 7 | 7 | 7 | 7 | 5 | 6 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 6 | 6 | 7 | 6 | 7 | 7 | 7 | 7 | 7        |   |  |
|                                |             | 9 | 5 | 0 | 3 | 2 | 3 | 2 | 2 | 1 | 6 | 1 | 2 | 2 | 3 | 9 | 3 | 2 | 9 | 3 | 2 | 9 | 3 | 2 | 9 | 2        |   |  |
|                                |             | 2 | 0 | 1 | 0 | 9 | 0 | 9 | 9 | 9 | 9 | 5 | 9 | 9 | 9 | 9 | 0 | 8 | 3 | 4 | 9 | 7 | 7 | 8 | 9 | 9        |   |  |
|                                |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |   |  |
|                                |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |   |  |
|                                |             | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2        |   |  |
|                                |             | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5        |   |  |
|                                |             | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0        |   |  |
| Sarcoma                        |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   | 1        |   |  |
| Tooth                          |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + | 5        |   |  |
| <b>CARDIOVASCULAR SYSTEM</b>   |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |   |  |
| Blood Vessel                   |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50       |   |  |
| Heart                          |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50       |   |  |
| Fibrosarcoma, Metastatic, Lung |             | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 1 |  |
| Lymphoma Malignant             |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 1 |  |
| <b>ENDOCRINE SYSTEM</b>        |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |   |  |
| Adrenal Cortex                 |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50       |   |  |
| Adrenal Medulla                |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50       |   |  |
| Leukemia Mononuclear           |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 1 |  |
| Pheochromocytoma Benign        |             | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 3 |  |
| Islets, Pancreatic             |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50       |   |  |
| Adenoma                        |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 1 |  |
| Parathyroid Gland              |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | M | M | + | + | + | M | 44       |   |  |
| Pituitary Gland                |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50       |   |  |
| Pars Distalis, Adenoma         |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X | X | X | X | X | X | X | X | X | 29       |   |  |
| Pars Distalis, Carcinoma       |             | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X | X | X | X | X | X | X | X | X | 1        |   |  |
| Thyroid Gland                  |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50       |   |  |
| C-cell, Adenoma                |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   | X |   |   |   |   |   |   |          | 5 |  |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

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## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

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First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

| FISCHER 344 RATS FEMALE  | 0.0 G/KG | DAY ON TEST |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |   |
|--------------------------|----------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|---|
|                          |          |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          |   |
| ANIMAL ID                |          | 6           | 4 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 6 | 6 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 6 | 6 | 7 | 6 | 7 | 7 | 7 |          |   |
|                          |          | 9           | 5 | 0 | 3 | 2 | 3 | 2 | 2 | 1 | 6 | 6 | 1 | 2 | 2 | 3 | 9 | 3 | 3 | 2 | 9 | 6 | 2 | 3 | 2 | 2 | 2        |   |
|                          |          | 2           | 0 | 1 | 0 | 9 | 0 | 9 | 9 | 9 | 9 | 9 | 5 | 9 | 9 | 9 | 3 | 0 | 3 | 0 | 8 | 3 | 4 | 9 | 7 | 8 | 9        |   |
|                          |          | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |   |
|                          |          | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |   |
|                          |          | 2           | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2        |   |
|                          |          | 2           | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5        |   |
|                          |          | 6           | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |          |   |
| Follicular Cell, Adenoma |          |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 1 |

## GENERAL BODY SYSTEM

NONE

## GENITAL SYSTEM

|                          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |   |
|--------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|---|
| Clitoral Gland           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |
| Adenoma                  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 2 |
| Carcinoma                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 |
| Carcinoma, Multiple      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 |
| Ovary                    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |
| Cystadenoma              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 |
| Uterus                   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |
| Polyp Stromal            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 6 |
| Sarcoma Stromal          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 |
| Bilateral, Polyp Stromal |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 |

## HEMATOPOIETIC SYSTEM

|                                 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |   |
|---------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|---|
| Bone Marrow                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |
| Lymphoma Malignant              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 |
| Lymph Node                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 |
| Mediastinal, Lymphoma Malignant |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 |
| Pancreatic, Lymphoma Malignant  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 |

|                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Lymph Node, Mandibular | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | 0 |
|------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

\* .. Total animals with tissue examined microscopically; Total animals with tumor

M .. Missing tissue

+ .. Tissue examined microscopically

A .. Autolysis precludes evaluation

X .. Lesion present

BLANK .. Not examined microscopically

I .. Insufficient tissue

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

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Lab: BAT

| FISCHER 344 RATS FEMALE       | DAY ON TEST |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |          |
|-------------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|----------|
|                               |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          |          |
| 0.0 G/KG                      | ANIMAL ID   | 6 | 4 | 7 | 7 | 7 | 7 | 7 | 5 | 6 | 6 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 6 | 6 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7        | * TOTALS |
|                               |             | 9 | 5 | 0 | 3 | 2 | 3 | 2 | 2 | 1 | 6 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 6 | 6 | 7 | 6 | 7 | 7 | 2 | 2 | 2 | 2        |          |
| Lymph Node, Mesenteric        |             | 2 | 0 | 1 | 0 | 9 | 0 | 9 | 9 | 9 | 5 | 9 | 9 | 9 | 9 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3        | 50       |
| Leukemia Mononuclear          |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1        |          |
| Lymphoma Malignant            |             | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2        | 1        |
| Spleen                        |             | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2        | 50       |
| Leukemia Mononuclear          |             | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3        | 5        |
| Lymphoma Malignant            |             | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 0        |          |
| Thymus                        |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +        | 50       |
| Lymphoma Malignant            |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 1        |          |
| <b>INTEGUMENTARY SYSTEM</b>   |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |          |
| Mammary Gland                 |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +        | 50       |
| Adenolipoma                   |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 1        |
| Adenoma                       |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 2        |
| Carcinoma                     |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 1        |
| Fibroadenoma                  |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 14       |
| Fibroadenoma, Multiple        |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 10       |
| Skin                          |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50       |          |
| Subcutaneous Tissue, Fibroma  |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 1        |          |
| <b>MUSCULOSKELETAL SYSTEM</b> |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |          |
| Bone                          |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50       |          |
| Skeletal Muscle               |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          | 1        |
| <b>NERVOUS SYSTEM</b>         |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |          |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

| FISCHER 344 RATS FEMALE      | DAY ON TEST |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |          |   |
|------------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|----------|---|
|                              |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          |          |   |
| 0.0 G/KG                     | ANIMAL ID   | 6 | 4 | 7 | 7 | 7 | 7 | 7 | 5 | 6 | 6 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 6 | 6 | 7 | 6 | 7 | 7 | 7 | 7 | 7        | * TOTALS |   |
|                              |             | 9 | 5 | 0 | 3 | 2 | 3 | 2 | 2 | 1 | 6 | 1 | 2 | 2 | 3 | 9 | 3 | 2 | 9 | 3 | 2 | 9 | 3 | 2 | 3 | 2 | 2        | 2        |   |
|                              |             | 2 | 0 | 1 | 0 | 9 | 0 | 9 | 9 | 9 | 9 | 5 | 9 | 9 | 9 | 3 | 0 | 3 | 0 | 8 | 3 | 4 | 9 | 7 | 2 | 9 | 8        | 9        |   |
|                              |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        | 0        |   |
|                              |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        | 0        |   |
|                              |             | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2        | 2        |   |
|                              |             | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4        | 5        |   |
|                              |             | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 0        | 0        |   |
| Brain                        |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +        | 50       |   |
| <b>RESPIRATORY SYSTEM</b>    |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |          |   |
| Lung                         |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +        | 50       |   |
| Leukemia Mononuclear         |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |          | 3 |
| Lymphoma Malignant           |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |          | 1 |
| Mediastinum, Fibrosarcoma    |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |          | 1 |
| Nose                         |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +        | 50       |   |
| Trachea                      |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +        | 50       |   |
| <b>SPECIAL SENSES SYSTEM</b> |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |          |   |
| Ear                          |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |          | 1 |
| Neural Crest Tumor           |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |          | 1 |
| Eye                          |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +        | 50       |   |
| Harderian Gland              |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +        | 50       |   |
| <b>URINARY SYSTEM</b>        |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |          |   |
| Kidney                       |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +        | 50       |   |
| Leukemia Mononuclear         |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |          | 1 |
| Urinary Bladder              |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +        | 50       |   |
| <b>SYSTEMIC LESIONS</b>      |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |          |   |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

| FISCHER 344 RATS FEMALE | 0.0 G/KG | ANIMAL ID | DAY ON TEST |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |
|-------------------------|----------|-----------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|
|                         |          |           | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |          |
|                         |          |           | 6           | 4 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 6 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 6 | 6 | 7 | 7        |
|                         |          |           | 9           | 5 | 0 | 3 | 2 | 3 | 2 | 2 | 1 | 6 | 6 | 1 | 2 | 2 | 3 | 9 | 3 | 2 | 9 | 6 | 2        |
|                         |          |           | 2           | 2 | 0 | 1 | 0 | 9 | 0 | 9 | 9 | 9 | 5 | 9 | 9 | 0 | 3 | 0 | 8 | 3 | 4 | 9 | 7        |
|                         |          |           |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |
|                         |          |           |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        |
|                         |          |           |             | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2        |
|                         |          |           |             | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 5        |
|                         |          |           |             | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5        |

Multiple Organ

Adenolipoma

Leukemia Mononuclear

Lymphoma Malignant

+ +

X

X

50

1

5

1

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

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TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

DAY ON TEST

**FISCHER 344 RATS FEMALE****0.1 G/KG**

ANIMAL ID

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 6 | 7 | 0 | 7 | 0 | 7 |
| 2 | 3 | 7 | 2 | 2 | 3 | 3 | 3 | 2 | 3 | 3 | 0 | 7 | 7 | 2 | 2 | 2 | 2 | 3 | 3 | 5 | 3 | 2 | 5 | 2 | 2 | 3 |
| 7 | 9 | 8 | 9 | 9 | 0 | 0 | 8 | 0 | 0 | 0 | 5 | 0 | 9 | 8 | 9 | 0 | 0 | 0 | 0 | 1 | 9 | 1 | 8 | 0 | 7 | 0 |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 5 | 5 |

females  
(cont...)**ALIMENTARY SYSTEM**

Esophagus

+ +

Intestine Large, Cecum

+ +

Intestine Large, Colon

+ +

Intestine Large, Rectum

+ +

Intestine Small, Duodenum

+ +

Intestine Small, Ileum

+ +

Intestine Small, Jejunum

+ +

Liver

+ +

Leukemia Mononuclear

X X

Pheochromocytoma Malignant, Metastatic,  
Adrenal Medulla

Mesentery

+ +

Oral Mucosa

+

Squamous Cell Papilloma

X

Pancreas

+ +

Salivary Glands

+ +

Stomach, Forestomach

+ +

\* .. Total animals with tissue examined microscopically; Total animals with tumor

M .. Missing tissue

+ .. Tissue examined microscopically

A .. Autolysis precludes evaluation

X .. Lesion present

BLANK .. Not examined microscopically

I .. Insufficient tissue

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

| FISCHER 344 RATS FEMALE      | 0.1 G/KG | ANIMAL ID | DAY ON TEST |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |   | females<br>(cont...) |   |   |
|------------------------------|----------|-----------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|---|----------------------|---|---|
|                              |          |           | 0727        | 0632 | 0672 | 0723 | 0733 | 0723 | 0733 | 0703 | 0672 | 0722 | 0722 | 0729 | 0728 | 0729 | 0730 | 0531 | 0629 | 0751 | 0728 | 0720 | 0722 | 0722 | 0722 |   |                      |   |   |
| Stomach, Glandular           |          |           | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | + |                      |   |   |
| Tooth                        |          |           |             |      | +    |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |   |                      |   |   |
| <b>CARDIOVASCULAR SYSTEM</b> |          |           |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |   |                      |   |   |
| Blood Vessel                 |          |           | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | + |                      |   |   |
| Heart                        |          |           | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | + |                      |   |   |
| Leukemia Mononuclear         |          |           | X           |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |   |                      | X |   |
| <b>ENDOCRINE SYSTEM</b>      |          |           |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |   |                      |   |   |
| Adrenal Cortex               |          |           | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | + | +                    |   |   |
| Adenoma                      |          |           |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |   |                      |   | X |
| Carcinoma                    |          |           |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |   |                      |   |   |
| Leukemia Mononuclear         |          |           | X           |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |   |                      |   | X |
| Adrenal Medulla              |          |           | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | + | +                    |   |   |
| Leukemia Mononuclear         |          |           | X           |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |   |                      |   | X |
| Pheochromocytoma Benign      |          |           |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |   |                      |   |   |
| Pheochromocytoma Malignant   |          |           |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |   |                      |   |   |
| Islets, Pancreatic           |          |           | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | + | +                    |   |   |
| Adenoma                      |          |           |             |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |      |   |                      |   |   |
| Parathyroid Gland            |          |           | +           | +    | +    | +    | M    | +    | +    | +    | +    | +    | +    | M    | +    | +    | +    | +    | +    | M    | +    | +    | +    | +    | +    | + | +                    |   |   |
| Pituitary Gland              |          |           | +           | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | +    | + | +                    |   |   |
| Pars Distalis, Adenoma       |          |           | X           | X    |      |      |      | X    | X    |      | X    |      |      | X    |      | X    | X    | X    | X    | X    | X    | X    | X    | X    | X    | X | X                    |   |   |

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## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

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First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

| FISCHER 344 RATS FEMALE       | 0.1 G/KG | DAY ON TEST |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | females<br>(cont...) |  |  |
|-------------------------------|----------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------------------|--|--|
|                               |          |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |  |  |
|                               |          | ANIMAL ID   | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |                      |  |  |
|                               |          |             | 2 | 3 | 7 | 2 | 2 | 3 | 3 | 3 | 2 | 3 | 3 | 0 | 5 | 0 | 7 | 2 | 2 | 2 | 2 | 3 | 3 | 0 | 8 | 1 |                      |  |  |
|                               |          |             | 7 | 9 | 8 | 9 | 9 | 0 | 0 | 8 | 0 | 0 | 0 | 0 | 5 | 0 | 9 | 2 | 8 | 2 | 9 | 0 | 0 | 7 | 3 | 0 | 0                    |  |  |
| Leukemia Mononuclear          |          |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |  |  |
| Spleen                        |          |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |                      |  |  |
| Leukemia Mononuclear          |          |             | X |   |   | X |   |   |   |   |   |   |   |   |   |   | X | X |   |   |   | X |   |   |   |   |                      |  |  |
| Thymus                        |          |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |                      |  |  |
| Leukemia Mononuclear          |          |             | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |                      |  |  |
| Thymoma Benign                |          |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |                      |  |  |
| <b>INTEGUMENTARY SYSTEM</b>   |          |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |  |  |
| Mammary Gland                 |          |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |                      |  |  |
| Adenoma                       |          |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |  |  |
| Carcinoma                     |          |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |  |  |
| Fibroadenoma                  |          |             | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |                      |  |  |
| Fibroadenoma, Multiple        |          |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |   |                      |  |  |
| Skin                          |          |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |                      |  |  |
| <b>MUSCULOSKELETAL SYSTEM</b> |          |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |  |  |
| Bone                          |          |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |                      |  |  |
| <b>NERVOUS SYSTEM</b>         |          |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |  |  |
| Brain                         |          |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |                      |  |  |
| Leukemia Mononuclear          |          |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |   |   |                      |  |  |
| <b>RESPIRATORY SYSTEM</b>     |          |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |  |  |
| Lung                          |          |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |                      |  |  |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

**Test Type:** CHRONIC

## Route: GAVAGE

**Species/Strain:** RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kaya kaya extract

CAS Number: 9000-38-8

**Date Report Requested:** 09/21/2010

**Time Report Requested:** 09:10:56

**First Dose M/F:** 08/18/04 / 08/19/04

## Lab: BAT

|  |  | DAY ON TEST |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | females<br>(cont...) |  |
|--|--|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------------------|--|
| <b>FISCHER 344 RATS FEMALE</b>                             |  | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | females<br>(cont...) |  |
| <b>0.1 G/KG</b>  |  | 7           | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |                      |  |
|  |  | 2           | 3 | 7 | 2 | 2 | 3 | 3 | 3 | 2 | 3 | 3 | 0 | 5 | 0 | 9 | 8 | 8 | 9 | 0 |                      |  |
|  |  | 7           | 9 | 8 | 9 | 9 | 0 | 0 | 8 | 0 | 0 | 0 | 5 | 0 | 9 | 8 | 8 | 9 | 0 | 1 |                      |  |
|  |  | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |  |
|  |  | 0           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |  |
|  |  | 2           | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |                      |  |
|  |  | 5           | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 |                      |  |
|  |  | 1           | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |                      |  |
|  |  | 2           | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |                      |  |
| Carcinoma, Metastatic, Mammary Gland                       |  |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |  |
| Leukemia Mononuclear                                       |  | X           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |  |
| Pheochromocytoma Malignant, Metastatic,<br>Adrenal Medulla |  |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |  |
| X  |  |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |  |
| Nose   |  | +           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |  |
| Trachea  |  | +           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |  |
| <b>SPECIAL SENSES SYSTEM</b>                               |  |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |  |
| Eye  |  | +           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |  |
| Harderian Gland  |  | +           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |  |
| <b>URINARY SYSTEM</b>                                      |  |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |  |
| Kidney   |  | +           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |  |
| Leukemia Mononuclear                                       |  |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |  |
| Urinary Bladder  |  | +           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |  |
| <b>SYSTEMIC LESIONS</b>                                    |  |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |  |
| Multiple Organ   |  | +           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |  |
| Leukemia Mononuclear                                       |  | X           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |  |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

#### I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

**Test Type: CHRONIC**

## **Route: GAVAGE**

**Species/Strain:** RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kaya kaya extract

**CAS Number:** 9000-38-8

**Date Report Requested:** 09/21/2010

**Time Report Requested:** 09:10:56

**First Dose M/F:** 08/18/04 / 08/19/04

Lab: BAT

| FISCHER 344 RATS FEMALE | 0.1 G/KG | DAY ON TEST | ANIMAL ID                        |                                  |                                  |                                  |                                  |                                  |                                  |                                  |                                  |                                  |                                  |                                  |                                  |                                  |                                  |                                  |                                  |                                  |                                  |                                  |
|-------------------------|----------|-------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|
|                         |          |             | 00000000000000000000000000000000 | 00000000000000000000000000000000 | 00000000000000000000000000000000 | 00000000000000000000000000000000 | 00000000000000000000000000000000 | 00000000000000000000000000000000 | 00000000000000000000000000000000 | 00000000000000000000000000000000 | 00000000000000000000000000000000 | 00000000000000000000000000000000 | 00000000000000000000000000000000 | 00000000000000000000000000000000 | 00000000000000000000000000000000 | 00000000000000000000000000000000 | 00000000000000000000000000000000 | 00000000000000000000000000000000 | 00000000000000000000000000000000 | 00000000000000000000000000000000 | 00000000000000000000000000000000 | 00000000000000000000000000000000 |
| 7                       | 7        | 0           | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                |
| 2                       | 2        | 2           | 2                                | 2                                | 2                                | 2                                | 2                                | 2                                | 0                                | 8                                | 1                                | 2                                | 0                                | 0                                | 3                                | 3                                | 2                                | 0                                | 2                                | 3                                | 2                                | 2                                |
| 9                       | 9        | 8           | 9                                | 8                                | 9                                | 9                                | 1                                | 8                                | 5                                | 9                                | 5                                | 0                                | 5                                | 0                                | 2                                | 0                                | 9                                | 5                                | 2                                | 8                                | 2                                | 9                                |
| 0                       | 0        | 0           | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                |
| 0                       | 0        | 0           | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                | 0                                |
| 2                       | 2        | 2           | 2                                | 2                                | 2                                | 2                                | 2                                | 2                                | 2                                | 2                                | 2                                | 2                                | 2                                | 2                                | 2                                | 2                                | 2                                | 2                                | 2                                | 2                                | 2                                | 2                                |
| 7                       | 7        | 7           | 7                                | 7                                | 8                                | 8                                | 8                                | 8                                | 8                                | 8                                | 8                                | 8                                | 8                                | 8                                | 9                                | 9                                | 9                                | 9                                | 9                                | 9                                | 9                                | 9                                |
| 6                       | 7        | 8           | 9                                | 0                                | 1                                | 2                                | 3                                | 4                                | 5                                | 6                                | 7                                | 8                                | 9                                | 0                                | 1                                | 2                                | 3                                | 4                                | 5                                | 6                                | 7                                | 8                                |

# ALIMENTARY SYSTEM

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

#### I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

| FISCHER 344 RATS FEMALE      | 0.1 G/KG | ANIMAL ID | DAY ON TEST      |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    | * TOTALS |    |
|------------------------------|----------|-----------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|---|----|----------|----|
|                              |          |           | 0<br>7<br>2<br>9 | 0<br>7<br>2<br>9 | 0<br>7<br>2<br>9 | 0<br>7<br>2<br>9 | 0<br>7<br>2<br>9 | 0<br>6<br>1<br>8 |   |    |          |    |
| Stomach, Glandular           |          |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | 50 |          |    |
| Tooth                        |          |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    | 3        |    |
| <b>CARDIOVASCULAR SYSTEM</b> |          |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    |          |    |
| Blood Vessel                 |          |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | 50 |          |    |
| Heart                        |          |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | 50 |          |    |
| Leukemia Mononuclear         |          |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    |          | 3  |
| <b>ENDOCRINE SYSTEM</b>      |          |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    |          |    |
| Adrenal Cortex               |          |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | +  | 50       |    |
| Adenoma                      |          |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    |          | 1  |
| Carcinoma                    |          |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    |          | X  |
| Leukemia Mononuclear         |          |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    |          | 4  |
| Adrenal Medulla              |          |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | +  | 50       |    |
| Leukemia Mononuclear         |          |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    |          | 3  |
| Pheochromocytoma Benign      |          |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    |          | 1  |
| Pheochromocytoma Malignant   |          |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    |          | 1  |
| Islets, Pancreatic           |          |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | +  | 50       |    |
| Adenoma                      |          |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    |          | 1  |
| Parathyroid Gland            |          |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | +  | 47       |    |
| Pituitary Gland              |          |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | +  | 50       |    |
| Pars Distalis, Adenoma       |          |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    |          | 20 |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

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TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

| FISCHER 344 RATS FEMALE<br>0.1 G/KG | DAY ON TEST<br>ANIMAL ID |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   | * TOTALS |  |
|-------------------------------------|--------------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|---|----------|--|
|                                     |                          | 0<br>7<br>2<br>9 | 0<br>7<br>2<br>9 | 0<br>7<br>2<br>9 | 0<br>7<br>2<br>9 | 0<br>7<br>2<br>9 | 0<br>7<br>2<br>9 | 0<br>6<br>1<br>5 | 0<br>6<br>2<br>9 | 0<br>6<br>0<br>5 | 0<br>0<br>3<br>0 | 0<br>7<br>3<br>2 | 0<br>7<br>3<br>0 | 0<br>7<br>2<br>9 | 0<br>7<br>2<br>9 | 0<br>7<br>2<br>8 | 0<br>6<br>2<br>8 | 0<br>7<br>2<br>9 | 0<br>6<br>2<br>9 | 0<br>7<br>2<br>9 | 0<br>6<br>2<br>9 | 0<br>7<br>2<br>9 | 0<br>6<br>2<br>9 | 0<br>7<br>2<br>9 |   |          |  |
| Thyroid Gland<br>C-cell, Adenoma    |                          | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | 50<br>6  |  |
| X                                   |                          |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |          |  |

## GENERAL BODY SYSTEM

NONE

## GENITAL SYSTEM

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |              |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------|
| Clitoral Gland<br>Adenoma<br>Carcinoma          | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49<br>7<br>1 |
| Ovary   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50           |
| Uterus<br>Leukemia Mononuclear<br>Polyp Stromal | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50<br>1<br>9 |

## HEMATOPOIETIC SYSTEM

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |             |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-------------|
| Bone Marrow   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |             |
| Lymph Node<br>Mediastinal, Leukemia Mononuclear<br>Pancreatic, Leukemia Mononuclear |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 3<br>3<br>2 |
| Lymph Node, Mandibular  | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | 0 |    |             |
| Lymph Node, Mesenteric  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |             |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

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TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

|                               |  | DAY ON TEST |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |
|-------------------------------|--|-------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|
| FISCHER 344 RATS FEMALE       |  | 0.1 G/KG    | ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | * TOTALS |
|                               |  |             |           | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |          |
|                               |  |             |           | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 0 | 8 | 1 | 5 | 9 | 5 | 5 | 0 | 3 | 3 | 3 | 2 | 9 | 5 | 0 | 2 |          |
|                               |  |             |           | 9 | 9 | 8 | 9 | 8 | 9 | 9 | 1 | 8 | 5 | 9 | 5 | 5 | 0 | 2 | 2 | 9 | 2 | 9 | 0 | 2 | 2 | 9 | 2        |
| Leukemia Mononuclear          |  |             |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 4        |
| Spleen                        |  |             |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 50       |
| Leukemia Mononuclear          |  |             |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 10       |
| Thymus                        |  |             |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 50       |
| Leukemia Mononuclear          |  |             |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 4        |
| Thymoma Benign                |  |             |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1        |
| <b>INTEGUMENTARY SYSTEM</b>   |  |             |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |
| Mammary Gland                 |  |             |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 50       |
| Adenoma                       |  |             |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1        |
| Carcinoma                     |  |             |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 3        |
| Fibroadenoma                  |  |             |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 17       |
| Fibroadenoma, Multiple        |  |             |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 7        |
| Skin                          |  |             |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 50       |
| <b>MUSCULOSKELETAL SYSTEM</b> |  |             |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |
| Bone                          |  |             |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 50       |
| <b>NERVOUS SYSTEM</b>         |  |             |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |
| Brain                         |  |             |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 50       |
| Leukemia Mononuclear          |  |             |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2        |
| <b>RESPIRATORY SYSTEM</b>     |  |             |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |          |
| Lung                          |  |             |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 50       |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

| FISCHER 344 RATS FEMALE                                    | 0.1 G/KG | ANIMAL ID | DAY ON TEST      |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    | * TOTALS |
|--|----------|-----------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|---|----|----------|
|  |          |           | 0<br>7<br>2<br>9 | 0<br>7<br>2<br>9 | 0<br>7<br>2<br>9 | 0<br>7<br>2<br>9 | 0<br>6<br>1<br>5 | 0<br>6<br>2<br>9 | 0<br>0<br>5<br>0 | 0<br>0<br>3<br>2 | 0<br>0<br>2<br>9 |   |    |          |
| Carcinoma, Metastatic, Mammary Gland                       |          |           | X                |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    | 1        |
| Leukemia Mononuclear                                       |          |           |                  | X                |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    | 5        |
| Pheochromocytoma Malignant, Metastatic,<br>Adrenal Medulla |          |           |                  |                  | X                |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    | 1        |
| Nose   |          |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | 50 |          |
| Trachea  |          |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | 50 |          |
| <b>SPECIAL SENSES SYSTEM</b>                               |          |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    |          |
| Eye  |          |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | 50 |          |
| Harderian Gland  |          |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | 50 |          |
| <b>URINARY SYSTEM</b>                                      |          |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    |          |
| Kidney   |          |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | 50 |          |
| Leukemia Mononuclear                                       |          |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    | 4        |
| Urinary Bladder  |          |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | 50 |          |
| <b>SYSTEMIC LESIONS</b>                                    |          |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    |          |
| Multiple Organ   |          |           | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | 50 |          |
| Leukemia Mononuclear                                       |          |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    | 11       |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

| FISCHER 344 RATS FEMALE       | 0.3 G/KG | DAY ON TEST |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | females<br>(cont...) |  |
|-------------------------------|----------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------------------|--|
|                               |          |             | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |  |
| ANIMAL ID                     |          | 0           | 7 | 0 | 0 | 6 | 5 | 5 | 6 | 6 | 7 | 6 | 7 | 7 | 7 | 5 | 4 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 |                      |  |
|                               |          | 5           | 0 | 3 | 9 | 2 | 3 | 1 | 1 | 1 | 2 | 8 | 2 | 2 | 2 | 3 | 3 | 5 | 8 | 2 | 2 | 2 | 2 | 2 | 3 | 1 | 3 | 3                    |  |
|                               |          | 1           | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 2 | 2 | 2 | 2 | 5                    |  |
| Esophagus                     |          |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +                    |  |
| Periesophageal Tissue, Lipoma |          |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |  |
| Intestine Large, Cecum        |          |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +                    |  |
| Intestine Large, Colon        |          |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +                    |  |
| Intestine Large, Rectum       |          |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +                    |  |
| Intestine Small, Duodenum     |          |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +                    |  |
| Intestine Small, Ileum        |          |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +                    |  |
| Intestine Small, Jejunum      |          |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +                    |  |
| Liver                         |          |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +                    |  |
| Leukemia Mononuclear          |          |             | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |  |
| Mesentery                     |          |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + |   |   |   |   |   |   |   |   |                      |  |
| Oral Mucosa                   |          |             | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |  |
| Squamous Cell Papilloma       |          |             | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |  |
| Pancreas                      |          |             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | +                    |  |
| Adenoma, Mixed Cell           |          |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |  |
| Leukemia Mononuclear          |          |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |  |
| Acinus, Adenoma               |          |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |                      |  |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

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TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

| FISCHER 344 RATS FEMALE<br>0.3 G/KG | DAY ON TEST<br>ANIMAL ID |   |  |   |   |  |   |  |  |  |  |  |  |  |   |   |   |   |   |   |   |   |   |   |   |   | <b>females<br/>(cont...)</b> |
|-------------------------------------|--------------------------|---|--|---|---|--|---|--|--|--|--|--|--|--|---|---|---|---|---|---|---|---|---|---|---|---|------------------------------|
|                                     |                          | 0<br>7<br>0<br>5<br>0<br>0<br>8<br>0<br>0<br>0<br>0<br>0<br>3<br>3<br>3<br>0<br>1 | 0<br>0<br>9<br>2<br>3<br>6<br>8<br>8<br>0<br>0<br>0<br>0<br>9<br>3<br>3<br>3<br>0<br>2 | 0<br>5<br>1<br>2<br>2<br>6<br>8<br>9<br>0<br>0<br>0<br>0<br>1<br>3<br>3<br>0<br>7 | 0<br>6<br>1<br>2<br>2<br>9<br>7<br>9<br>1<br>9<br>0<br>0<br>0<br>0<br>1<br>1<br>1<br>1<br>1 | 0<br>7<br>2<br>2<br>9<br>7<br>9<br>1<br>9<br>0<br>0<br>0<br>0<br>1<br>1<br>1<br>1<br>1 | 0<br>4<br>3<br>3<br>9<br>5<br>9<br>9<br>9<br>9<br>0<br>0<br>0<br>0<br>1<br>1<br>1<br>1<br>1 | 0<br>6<br>5<br>8<br>8<br>6<br>8<br>8<br>2<br>2<br>9<br>0<br>0<br>0<br>0<br>1<br>1<br>1<br>1<br>1 | 0<br>6<br>5<br>8<br>8<br>6<br>8<br>8<br>2<br>2<br>9<br>0<br>0<br>0<br>0<br>1<br>1<br>1<br>1<br>1 | 0<br>7<br>2<br>2<br>9<br>7<br>9<br>1<br>9<br>0<br>0<br>0<br>0<br>1<br>1<br>1<br>1<br>1 | 0<br>7<br>2<br>2<br>9<br>7<br>9<br>1<br>9<br>0<br>0<br>0<br>0<br>1<br>1<br>1<br>1<br>1 | 0<br>7<br>2<br>2<br>9<br>7<br>9<br>1<br>9<br>0<br>0<br>0<br>0<br>1<br>1<br>1<br>1<br>1 | 0<br>7<br>2<br>2<br>9<br>7<br>9<br>1<br>9<br>0<br>0<br>0<br>0<br>1<br>1<br>1<br>1<br>1 | 0<br>7<br>2<br>2<br>9<br>7<br>9<br>1<br>9<br>0<br>0<br>0<br>0<br>1<br>1<br>1<br>1<br>1 | 0<br>5<br>1<br>3<br>8<br>5<br>9<br>0<br>2<br>2<br>0<br>0<br>0<br>0<br>0<br>2<br>2 | 0<br>7<br>3<br>3<br>8<br>5<br>9<br>0<br>2<br>2<br>0<br>0<br>0<br>0<br>0<br>2<br>2 |   |   |   |   |   |   |   |   |   |   |                              |
| Salivary Glands                     |                          | +   | +  | +   | +   | +  | +   | +  | +  | +  | +  | +  | +  | +  | +   | +   | + | + | + | + | + | + | + | + | + | + |                              |
| Stomach, Forestomach                |                          | +   | +  | +   | +   | +  | +   | +  | +  | +  | +  | +  | +  | +  | +   | +   | + | + | + | + | + | + | + | + | + | + |                              |
| Stomach, Glandular                  |                          | +   | +  | +   | +   | +  | +   | +  | +  | +  | +  | +  | +  | +  | +   | +   | + | + | + | + | + | + | + | + | + | + |                              |
| Tooth                               |                          | +   |  |   |   |  |   |  |  |  |  |  |  |  |   |   |   |   |   |   |   |   |   |   |   |   |                              |
| <b>CARDIOVASCULAR SYSTEM</b>        |                          |   |  |   |   |  |   |  |  |  |  |  |  |  |   |   |   |   |   |   |   |   |   |   |   |   |                              |
| Blood Vessel                        |                          | +   | +  | +   | +   | +  | +   | +  | +  | +  | +  | +  | +  | +  | +   | +   | + | + | + | + | + | + | + | + | + | + |                              |
| Heart                               |                          | +   | +  | +   | +   | +  | +   | +  | +  | +  | +  | +  | +  | +  | +   | +   | + | + | + | + | + | + | + | + | + | + |                              |
| Leukemia Mononuclear                |                          |   |  |   |   |  |   |  |  |  |  |  |  |  |   |   |   |   |   |   |   |   |   |   |   |   |                              |
| <b>ENDOCRINE SYSTEM</b>             |                          |   |  |   |   |  |   |  |  |  |  |  |  |  |   |   |   |   |   |   |   |   |   |   |   |   |                              |
| Adrenal Cortex                      |                          | +   | +  | +   | +   | +  | +   | +  | +  | +  | +  | +  | +  | +  | +   | +   | + | + | + | + | + | + | + | + | + | + |                              |
| Leukemia Mononuclear                |                          |   |  |   |   |  |   |  |  |  |  |  |  |  |   |   |   |   |   |   |   |   |   |   |   |   |                              |
| Adrenal Medulla                     |                          | +   | +  | +   | +   | +  | +   | +  | +  | +  | +  | +  | +  | +  | +   | +   | + | + | + | + | + | + | + | + | + | + |                              |
| Leukemia Mononuclear                |                          |   |  |   |   |  |   |  |  |  |  |  |  |  |   |   |   |   |   |   |   |   |   |   |   |   |                              |
| Pheochromocytoma Benign             |                          |   |  |   |   |  |   |  |  |  |  |  |  |  |   |   |   |   |   |   |   |   |   |   |   |   |                              |
| Islets, Pancreatic                  |                          | +   | +  | +   | +   | +  | +   | +  | +  | +  | +  | +  | +  | +  | +   | +   | + | + | + | + | + | + | + | + | + | + |                              |
| Parathyroid Gland                   |                          | M   | +  | +   | +   | +  | +   | +  | +  | +  | +  | +  | +  | +  | +   | +   | + | M | + | + | + | + | + | + | M | + | +                            |
| Pituitary Gland                     |                          | +   | +  | +   | +   | +  | +   | +  | +  | +  | +  | +  | +  | +  | +   | +   | + | X | + | + | + | + | + | + | X | + | +                            |
| Pars Distalis, Adenoma              |                          | X   | X  | X   | X   | X  | X   | X  | X  | X  | X  | X  | X  | X  | X   | X   | X | X | X | X | X | X | X | X | X | X | X                            |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

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TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

**P04: NEOPLASMS BY INDIVIDUAL ANIMAL**

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

| FISCHER 344 RATS FEMALE | DAY ON TEST |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        | females<br>(cont...) |  |
|-------------------------|-------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|----------------------|--|
|                         |             | 0<br>7 | 0<br>7 | 0<br>0 | 0<br>6 | 0<br>5 | 0<br>5 | 0<br>6 | 0<br>6 | 0<br>7 | 0<br>6 | 0<br>7 | 0<br>7 | 0<br>7 | 0<br>5 | 0<br>4 | 0<br>6 | 0<br>6 | 0<br>7 | 0<br>7 | 0<br>7 | 0<br>7 | 0<br>5 | 0<br>7 | 0<br>7 | 0<br>0 | 0<br>0 |                      |  |
| 0.3 G/KG                | ANIMAL ID   | 0<br>0 | 3<br>3 | 9<br>3 | 2<br>3 | 3<br>1 | 1<br>1 | 2<br>8 | 8<br>9 | 1<br>9 | 2<br>9 | 2<br>9 | 2<br>9 | 3<br>9 | 3<br>9 | 5<br>2 | 8<br>8 | 2<br>8 | 2<br>9 | 2<br>9 | 2<br>9 | 2<br>9 | 2<br>9 | 2<br>8 | 2<br>0 | 2<br>0 | 2<br>0 | 2<br>0               |  |
| Lymph Node, Mesenteric  |             | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +                    |  |
| Leukemia Mononuclear    |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        | X      |        |        |                      |  |
| Spleen                  |             | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +                    |  |
| Leukemia Mononuclear    |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        | X      |        |        |                      |  |
| Thymus                  |             | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | M      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +      | +                    |  |
| Leukemia Mononuclear    |             |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |                      |  |

**INTEGUMENTARY SYSTEM**

|                                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Mammary Gland                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |  |
| Carcinoma                         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |  |
| Fibroadenoma                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |  |
| Fibroadenoma, Multiple            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |  |
| Skin                              | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |   |  |
| Subcutaneous Tissue, Fibroma      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |  |
| Subcutaneous Tissue, Lipoma       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
| Subcutaneous Tissue, Osteosarcoma |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |

**MUSCULOSKELETAL SYSTEM**

|                                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |        |  |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|--|
| Bone                           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |        |  |
| Osteoma                        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X      |  |
| Osteosarcoma                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |        |  |
| Osteosarcoma, Metastatic, Skin |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |        |  |
| Skeletal Muscle                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | +<br>X |  |
| Rhabdomyosarcoma               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |        |  |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

| FISCHER 344 RATS FEMALE | 0.3 G/KG | DAY ON TEST | ANIMAL ID |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | females<br>(cont...) |
|-------------------------|----------|-------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------------------|
|                         |          |             | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |                      |
|                         |          | 7           | 7         | 0 | 0 | 6 | 5 | 5 | 6 | 6 | 7 | 6 | 7 | 7 | 7 | 5 | 4 | 6 | 6 | 7 | 7 | 7 | 7 | 5 | 7 | 7 |                      |
|                         |          | 0           | 0         | 3 | 9 | 2 | 3 | 1 | 1 | 1 | 2 | 8 | 2 | 2 | 2 | 3 | 3 | 5 | 8 | 2 | 2 | 2 | 2 | 3 | 1 | 3 | 3                    |
|                         |          | 5           | 0         | 8 | 8 | 2 | 9 | 5 | 8 | 9 | 1 | 9 | 9 | 9 | 9 | 9 | 2 | 8 | 8 | 2 | 9 | 9 | 0 | 8 | 0 | 0 | 0                    |
|                         |          | 0           | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                    |
|                         |          | 0           | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0                    |
|                         |          | 3           | 3         | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3                    |
|                         |          | 0           | 0         | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2                    |
|                         |          | 1           | 2         | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 2 | 3 | 4 | 5                    |

## NERVOUS SYSTEM

Brain

+ +

Peripheral Nerve

Trigeminal, Leukemia Mononuclear

Spinal Cord

## RESPIRATORY SYSTEM

Lung

Alveolar/Bronchiolar Adenoma, Multiple  
Leukemia Mononuclear  
Osteosarcoma, Metastatic, Skin

+ +

X

X

Nose

+ +

Trachea

+ +

## SPECIAL SENSES SYSTEM

Eye

+ +

Harderian Gland

+ +

## URINARY SYSTEM

Kidney

Leukemia Mononuclear

+ +

X

\* .. Total animals with tissue examined microscopically; Total animals with tumor

M .. Missing tissue

+ .. Tissue examined microscopically

A .. Autolysis precludes evaluation

X .. Lesion present

BLANK .. Not examined microscopically

I .. Insufficient tissue

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

| FISCHER 344 RATS FEMALE<br>0.3 G/KG | DAY ON TEST<br>ANIMAL ID | females<br>(cont...)                    |   |                                      |                                      |                                      |                                      |                                      |                                      |                                      |                                      |                                      |                                      |                                      |                                      |                                      |                                      |                                      |                                      |                                      |  |  |  |  |  |  |
|-------------------------------------|--------------------------|---|---|--------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|--|--|--|--|--|--|
|                                     |                          | 0<br>7<br>0<br>5<br>5<br>0<br>8<br>8    | 0<br>9<br>2<br>3<br>1<br>9<br>8<br>2                | 0<br>6<br>3<br>2<br>9<br>5<br>8<br>2 | 0<br>6<br>1<br>1<br>9<br>9<br>9<br>1 | 0<br>7<br>2<br>2<br>9<br>9<br>9<br>1 | 0<br>5<br>3<br>3<br>9<br>9<br>9<br>1 | 4<br>4<br>3<br>3<br>9<br>9<br>9<br>1 | 0<br>6<br>5<br>5<br>2<br>2<br>8<br>8 | 0<br>6<br>8<br>8<br>2<br>8<br>8<br>1 | 0<br>7<br>2<br>2<br>9<br>8<br>9<br>2 | 0<br>7<br>2<br>2<br>9<br>9<br>9<br>0 | 0<br>5<br>3<br>3<br>8<br>8<br>8<br>0 | 0<br>7<br>3<br>3<br>1<br>8<br>9<br>1 | 0<br>5<br>3<br>3<br>0<br>2<br>2<br>0 | 0<br>7<br>3<br>3<br>1<br>2<br>2<br>0 | 0<br>5<br>3<br>3<br>0<br>2<br>2<br>0 | 0<br>7<br>3<br>3<br>1<br>2<br>2<br>0 | 0<br>5<br>3<br>3<br>0<br>2<br>2<br>0 | 0<br>7<br>3<br>3<br>1<br>2<br>2<br>0 |  |  |  |  |  |  |
|                                     |                          | Urinary Bladder<br>Leukemia Mononuclear | + |                                      |                                      |                                      |                                      |                                      |                                      |                                      |                                      |                                      |                                      |                                      |                                      |                                      |                                      |                                      |                                      |                                      |  |  |  |  |  |  |

## SYSTEMIC LESIONS

Multiple Organ  
Leukemia Mononuclear

+ X

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

|                         |  | DAY ON TEST |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | * TOTALS |   |   |   |   |   |   |   |
|-------------------------|--|-------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|---|---|---|---|---|---|---|
| FISCHER 344 RATS FEMALE |  | 0.3 G/KG    | ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                         |  |             |           | 7 | 6 | 7 | 7 | 6 | 7 | 7 | 5 | 7 | 6 | 7 | 6 | 5 | 6 | 7 | 6 | 7 | 6 | 7 | 6        | 7 | 6 | 7 | 6 | 7 | 7 | 0 |
|                         |  |             |           | 3 | 2 | 2 | 0 | 7 | 2 | 2 | 7 | 2 | 5 | 3 | 6 | 3 | 5 | 3 | 3 | 2 | 8 | 7 | 2        | 9 | 7 | 2 | 3 | 3 | 0 |   |
|                         |  |             |           | 0 | 9 | 9 | 5 | 2 | 9 | 8 | 9 | 3 | 0 | 4 | 2 | 8 | 0 | 2 | 8 | 7 | 9 | 7 | 9        | 0 | 8 | 9 | 2 | 0 |   |   |
|                         |  |             |           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        | 0 | 0 | 0 | 0 | 0 | 0 |   |
|                         |  |             |           | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0        | 0 | 0 | 0 | 0 | 0 |   |   |
|                         |  |             |           | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3        | 3 | 3 | 3 | 3 | 3 | 3 |   |
|                         |  |             |           | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4        | 4 | 4 | 4 | 4 | 4 | 5 |   |
|                         |  |             |           | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5        | 6 | 7 | 8 | 9 | 0 |   |   |

## ALIMENTARY SYSTEM

|                               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |   |
|-------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|---|
| Esophagus                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |
| Periesophageal Tissue, Lipoma |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 |
| Intestine Large, Cecum        | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |
| Intestine Large, Colon        | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |
| Intestine Large, Rectum       | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |
| Intestine Small, Duodenum     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |
| Intestine Small, Ileum        | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |
| Intestine Small, Jejunum      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |
| Liver                         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |
| Leukemia Mononuclear          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 6 |
| Mesentery                     | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 7 |
| Oral Mucosa                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 2 |
| Squamous Cell Papilloma       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 |
| Pancreas                      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |
| Adenoma, Mixed Cell           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 |
| Leukemia Mononuclear          |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 |
| Acinus, Adenoma               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

| FISCHER 344 RATS FEMALE<br>0.3 G/KG | DAY ON TEST<br>ANIMAL ID |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    | * TOTALS |    |
|-------------------------------------|--------------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|---|----|----------|----|
|                                     |                          | 0<br>7<br>3<br>0 | 0<br>6<br>2<br>9 | 0<br>7<br>2<br>9 | 0<br>6<br>7<br>2 | 0<br>7<br>2<br>9 | 0<br>5<br>2<br>9 | 0<br>7<br>2<br>9 | 0<br>6<br>3<br>3 | 0<br>6<br>3<br>4 | 0<br>5<br>2<br>8 | 0<br>6<br>3<br>0 | 0<br>7<br>2<br>2 | 0<br>6<br>2<br>8 | 0<br>7<br>2<br>9 | 0<br>6<br>2<br>9 | 0<br>7<br>2<br>9 | 0<br>6<br>2<br>9 | 0<br>7<br>2<br>9 | 0<br>6<br>2<br>9 | 0<br>7<br>2<br>9 | 0<br>6<br>2<br>9 | 0<br>7<br>2<br>9 |   |    |          |    |
| Salivary Glands                     |                          | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | 50 |          |    |
| Stomach, Forestomach                |                          | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | 50 |          |    |
| Stomach, Glandular                  |                          | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | 50 |          |    |
| Tooth                               |                          | +                |                  | +                |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    | 4        |    |
| <b>CARDIOVASCULAR SYSTEM</b>        |                          |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    |          |    |
| Blood Vessel                        |                          | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | +  | 50       |    |
| Heart                               |                          | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | +  | 50       |    |
| Leukemia Mononuclear                |                          | X                |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    |          | 1  |
| <b>ENDOCRINE SYSTEM</b>             |                          |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    |          |    |
| Adrenal Cortex                      |                          | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | +  | 50       |    |
| Leukemia Mononuclear                |                          | X                |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    |          | 2  |
| Adrenal Medulla                     |                          | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | +  | 50       |    |
| Leukemia Mononuclear                |                          | X                |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    |          | 1  |
| Pheochromocytoma Benign             |                          |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    |          |    |
| Islets, Pancreatic                  |                          | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | +  | 50       |    |
| Parathyroid Gland                   |                          | +                | +                | +                | +                | +                | +                | +                | M                | +                | M                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | M  | +        | 44 |
| Pituitary Gland                     |                          | +                | +                | +                | +                | +                | +                | +                | X                | X                | X                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | X  | 50       |    |
| Pars Distalis, Adenoma              |                          |                  |                  |                  |                  |                  |                  |                  | X                | X                | X                |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    |          | 24 |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

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TDMS No. 20007 - 05

Test Type: CHRONIC

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Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

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Lab: BAT

| FISCHER 344 RATS FEMALE<br>0.3 G/KG | DAY ON TEST<br>ANIMAL ID |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |    | * TOTALS |
|-------------------------------------|--------------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|----|----------|
|                                     |                          | 0<br>7<br>3<br>0 | 0<br>6<br>2<br>9 | 0<br>7<br>2<br>9 | 0<br>6<br>7<br>2 | 0<br>5<br>2<br>9 | 0<br>7<br>2<br>9 | 0<br>6<br>3<br>3 | 0<br>6<br>3<br>4 | 0<br>5<br>2<br>8 | 0<br>6<br>3<br>0 | 0<br>7<br>2<br>2 | 0<br>6<br>3<br>2 | 0<br>7<br>2<br>8 | 0<br>6<br>2<br>9 | 0<br>7<br>2<br>9 |    |          |
| Thyroid Gland                       |                          | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | 50 |          |
| C-cell, Adenoma                     |                          |                  |                  |                  |                  |                  |                  | X                |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |    | 5        |
| Follicular Cell, Adenoma            |                          |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |    | 1        |
| <b>GENERAL BODY SYSTEM</b>          |                          |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |    |          |
| NONE                                |                          |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |    |          |
| <b>GENITAL SYSTEM</b>               |                          |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |    |          |
| Clitoral Gland                      |                          | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | 50 |          |
| Adenoma                             |                          |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |    | 3        |
| Ovary                               |                          | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | 50 |          |
| Granulosa Cell Tumor Benign         |                          |                  | X                |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |    | 1        |
| Uterus                              |                          | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | 50 |          |
| Carcinosarcoma                      |                          |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |    | 1        |
| Polyp Stromal                       |                          |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |    | 8        |
| Sarcoma Stromal                     |                          |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |    | 1        |
| <b>HEMATOPOIETIC SYSTEM</b>         |                          |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |    |          |
| Bone Marrow                         |                          | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | 50 |          |
| Lymph Node                          |                          |                  | +                |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |    |          |
| Mediastinal, Leukemia Mononuclear   |                          |                  | X                |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |    |          |
| Pancreatic, Leukemia Mononuclear    |                          |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |    |          |
| Lymph Node, Mandibular              |                          | M                | M                | M                | M                | M                | M                | M                | M                | M                | M                | M                | M                | M                | M                | M                | M                | M                | M                | M                | M                | M                | M                | M                | 0  |          |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

| FISCHER 344 RATS FEMALE           | 0.3 G/KG | DAY ON TEST | ANIMAL ID |                  |                  |                  |                  |                  |                  |                  |             |             |             |             |             |             |             |             |             |             |             |             |             |             |             |             |    |    | * TOTALS |
|-----------------------------------|----------|-------------|-----------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|----|----|----------|
|                                   |          |             |           | 0<br>7<br>3<br>0 | 0<br>6<br>2<br>9 | 0<br>7<br>2<br>9 | 0<br>6<br>7<br>2 | 0<br>5<br>2<br>9 | 0<br>7<br>3<br>3 | 0<br>6<br>3<br>0 | 0<br>5<br>4 | 0<br>6<br>2 | 0<br>7<br>3 | 0<br>6<br>2 | 0<br>7<br>2 | 0<br>6<br>9 | 0<br>7<br>2 | 0<br>6<br>7 | 0<br>7<br>3 | 0<br>6<br>9 | 0<br>7<br>2 | 0<br>6<br>7 | 0<br>7<br>3 | 0<br>6<br>9 | 0<br>7<br>2 | 0<br>6<br>7 |    |    |          |
| Lymph Node, Mesenteric            |          | +           |           | +                | +                | +                | +                | +                | +                | +                | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | 50 |    |          |
| Leukemia Mononuclear              |          | X           |           |                  |                  |                  |                  |                  |                  |                  |             |             |             |             |             |             |             |             |             |             |             |             |             |             |             |             |    | 2  |          |
| Spleen                            |          | +           |           | +                | +                | +                | +                | +                | +                | +                | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | 50 |    |          |
| Leukemia Mononuclear              |          | X           |           |                  |                  |                  |                  |                  |                  |                  |             |             |             |             |             |             |             |             |             |             |             |             |             |             |             |             |    | 5  |          |
| Thymus                            |          | +           |           | +                | +                | +                | +                | +                | +                | +                | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | 49 |    |          |
| Leukemia Mononuclear              |          | X           |           |                  |                  |                  |                  |                  |                  |                  |             |             |             |             |             |             |             |             |             |             |             |             |             |             |             |             |    | 1  |          |
| <b>INTEGUMENTARY SYSTEM</b>       |          |             |           |                  |                  |                  |                  |                  |                  |                  |             |             |             |             |             |             |             |             |             |             |             |             |             |             |             |             |    |    |          |
| Mammary Gland                     |          | +           |           | +                | +                | +                | +                | +                | +                | +                | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +  | 50 |          |
| Carcinoma                         |          |             |           |                  |                  |                  |                  |                  |                  |                  |             |             |             |             |             |             |             |             |             |             |             |             |             |             |             |             |    |    | 1        |
| Fibroadenoma                      |          |             |           |                  |                  |                  |                  |                  |                  |                  |             |             |             |             |             |             |             |             |             |             |             |             |             |             |             |             |    |    | 13       |
| Fibroadenoma, Multiple            |          | X           |           |                  |                  |                  |                  |                  |                  |                  |             |             |             |             |             |             |             |             |             |             |             |             |             |             |             |             |    |    | 2        |
| Skin                              |          | +           |           | +                | +                | +                | +                | +                | +                | +                | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | 50 |    |          |
| Subcutaneous Tissue, Fibroma      |          |             |           |                  |                  |                  |                  |                  |                  |                  |             |             |             |             |             |             |             |             |             |             |             |             |             |             |             |             |    |    | 1        |
| Subcutaneous Tissue, Lipoma       |          |             |           |                  |                  |                  |                  |                  |                  |                  |             |             |             |             |             |             |             |             |             |             |             |             |             |             |             |             |    |    | 1        |
| Subcutaneous Tissue, Osteosarcoma |          |             |           |                  |                  |                  |                  |                  |                  |                  |             |             |             |             |             |             |             |             |             |             |             |             |             |             |             |             |    |    | 1        |
| <b>MUSCULOSKELETAL SYSTEM</b>     |          |             |           |                  |                  |                  |                  |                  |                  |                  |             |             |             |             |             |             |             |             |             |             |             |             |             |             |             |             |    |    |          |
| Bone                              |          | +           |           | +                | +                | +                | +                | +                | +                | +                | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +  | 50 |          |
| Osteoma                           |          |             |           |                  |                  |                  |                  |                  |                  |                  |             |             |             |             |             |             |             |             |             |             |             |             |             |             |             |             |    |    | 1        |
| Osteosarcoma                      |          |             |           |                  |                  |                  |                  |                  |                  |                  |             |             |             |             |             |             |             |             |             |             |             |             |             |             |             |             |    |    | 1        |
| Osteosarcoma, Metastatic, Skin    |          |             |           |                  |                  |                  |                  |                  |                  |                  |             |             |             |             |             |             |             |             |             |             |             |             |             |             |             |             |    |    | 1        |
| Skeletal Muscle                   |          | +           |           | +                | +                | +                | +                | +                | +                | +                | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +           | +  | 1  |          |
| Rhabdomyosarcoma                  |          |             |           |                  |                  |                  |                  |                  |                  |                  |             |             |             |             |             |             |             |             |             |             |             |             |             |             |             |             |    |    | 1        |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

DAY ON TEST

## FISCHER 344 RATS FEMALE

0.3 G/KG

ANIMAL ID

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7 | 6 | 7 | 7 | 6 | 7 | 7 | 7 | 5 | 7 | 6 | 7 | 6 | 5 | 6 | 7 | 6 | 7 | 7 | 6 | 7 | 7 | 6 | 7 |
| 3 | 2 | 2 | 0 | 7 | 2 | 2 | 2 | 7 | 2 | 5 | 3 | 6 | 3 | 5 | 3 | 2 | 8 | 7 | 2 | 9 | 0 | 3 | 0 |
| 0 | 9 | 9 | 5 | 2 | 9 | 9 | 8 | 9 | 3 | 0 | 4 | 2 | 8 | 0 | 2 | 8 | 7 | 2 | 9 | 7 | 0 | 8 | 2 |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 |
| 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |

\* TOTALS

## NERVOUS SYSTEM

Brain

+ 50

Peripheral Nerve

Trigeminal, Leukemia Mononuclear

+ X 1  
X 1

Spinal Cord

+ 1

## RESPIRATORY SYSTEM

Lung

Alveolar/Bronchiolar Adenoma, Multiple  
Leukemia Mononuclear  
Osteosarcoma, Metastatic, Skin+ 50  
X X 1  
X 4  
X 1

Nose

+ 50

Trachea

+ 50

## SPECIAL SENSES SYSTEM

Eye

+ 50

Harderian Gland

+ 50

## URINARY SYSTEM

Kidney

Leukemia Mononuclear

+ 50  
X 2

\* .. Total animals with tissue examined microscopically; Total animals with tumor

M .. Missing tissue

+ .. Tissue examined microscopically

A .. Autolysis precludes evaluation

X .. Lesion present

BLANK .. Not examined microscopically

I .. Insufficient tissue

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

| FISCHER 344 RATS FEMALE<br>0.3 G/KG | DAY ON TEST<br>ANIMAL ID |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    | * TOTALS |   |
|-------------------------------------|--------------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|---|----|----------|---|
|                                     |                          | 0<br>7<br>3<br>0 | 0<br>6<br>2<br>9 | 0<br>7<br>2<br>9 | 0<br>6<br>2<br>9 | 0<br>7<br>2<br>9 | 0<br>5<br>2<br>9 | 0<br>7<br>2<br>9 | 0<br>6<br>3<br>0 | 0<br>7<br>3<br>4 | 0<br>6<br>3<br>2 | 0<br>7<br>2<br>8 | 0<br>6<br>2<br>9 | 0<br>7<br>2<br>9 | 0<br>6<br>2<br>9 |   |    |          |   |
| Urinary Bladder                     |                          | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | 50 |          |   |
| Leukemia Mononuclear                |                          | X                |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    | 1        |   |
| <b>SYSTEMIC LESIONS</b>             |                          |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    | 50       |   |
| Multiple Organ                      |                          | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | + | +  | 6        |   |
| Leukemia Mononuclear                |                          | X                | X                |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |   |    |          | 1 |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

|                         |          | DAY ON TEST | 0<br>7<br>3<br>0      | 0<br>7<br>2<br>8      | 0<br>4<br>8<br>9      | 0<br>7<br>3<br>0      | 0<br>7<br>2<br>8      | 0<br>7<br>0<br>8      | 0<br>7<br>3<br>0      | 0<br>6<br>1<br>9      | 0<br>6<br>2<br>9 | 0<br>6<br>1<br>6 | 0<br>7<br>3<br>8 | 0<br>6<br>8<br>0 | 0<br>7<br>2<br>9 | 0<br>7<br>3<br>0 | 0<br>7<br>2<br>8 | 0<br>7<br>3<br>7 | 0<br>7<br>2<br>8 | 0<br>6<br>8<br>7 |             |                      |
|-------------------------|----------|-------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|-------------|----------------------|
|                         |          | ANIMAL ID   | 0<br>0<br>3<br>5<br>1 | 0<br>0<br>3<br>5<br>2 | 0<br>0<br>3<br>5<br>3 | 0<br>0<br>3<br>5<br>4 | 0<br>0<br>3<br>5<br>5 | 0<br>0<br>3<br>5<br>6 | 0<br>0<br>3<br>5<br>7 | 0<br>0<br>3<br>5<br>8 | 0<br>1<br>2      | 0<br>1<br>2 | females<br>(cont...) |
| FISCHER 344 RATS FEMALE | 1.0 G/KG |             |                       |                       |                       |                       |                       |                       |                       |                       |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |             |                      |

## ALIMENTARY SYSTEM

|                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Esophagus                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Cecum    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Colon    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Rectum   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Ileum    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Jejunum  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Liver                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Leukemia Mononuclear      |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Lymphoma Malignant        |   |   | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |
| Mesentery                 |   |   |   | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | + |
| Pancreas                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Salivary Glands           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Stomach, Forestomach      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Stomach, Glandular        | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Tooth                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

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TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

DAY ON TEST

## FISCHER 344 RATS FEMALE

1.0 G/KG

ANIMAL ID

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7 | 7 | 6 | 7 | 7 | 4 | 7 | 7 | 7 | 7 | 7 | 7 | 1 | 7 | 6 | 6 | 7 | 6 | 7 | 7 | 7 | 6 |
| 3 | 2 | 8 | 3 | 3 | 8 | 3 | 3 | 2 | 2 | 3 | 3 | 2 | 1 | 3 | 2 | 1 | 3 | 8 | 3 | 2 | 3 |
| 0 | 0 | 8 | 8 | 0 | 0 | 9 | 0 | 0 | 8 | 8 | 0 | 9 | 1 | 0 | 9 | 6 | 0 | 8 | 9 | 0 | 8 |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 |

females  
(cont...)

## CARDIOVASCULAR SYSTEM

Blood Vessel

+ +

Heart

+ +

Leukemia Mononuclear

X

Schwannoma Malignant, Metastatic, Lung

## ENDOCRINE SYSTEM

Adrenal Cortex

+ +

Leukemia Mononuclear

X

X

Adrenal Medulla

+ +

Leukemia Mononuclear

X

Pheochromocytoma Benign

X

Islets, Pancreatic

+ +

Parathyroid Gland

+ +

Adenoma

X

Pituitary Gland

+ +

Pars Distalis, Adenoma

X

X

Thyroid Gland

+ +

Bilateral, C-cell, Adenoma

X

X

C-cell, Adenoma

Follicular Cell, Adenoma

\* .. Total animals with tissue examined microscopically; Total animals with tumor

M .. Missing tissue

+ .. Tissue examined microscopically

A .. Autolysis precludes evaluation

X .. Lesion present

BLANK .. Not examined microscopically

I .. Insufficient tissue

TDMS No. 20007 - 05

**Test Type: CHRONIC**

## **Route: GAVAGE**

**Species/Strain:** RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kaya kaya extract

**CAS Number:** 9000-38-8

**Date Report Requested:** 09/21/2010

**Time Report Requested:** 09:10:56

**First Dose M/F:** 08/18/04 / 08/19/04

## Lab: BAT

| DAY ON TEST |      |                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-------------|------|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|             | MALE | females<br>(cont...) |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| ANIMAL ID   | 0    | 0                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|             | 7    | 7                    | 6 | 7 | 7 | 4 | 7 | 7 | 7 | 7 | 7 | 7 | 1 | 7 | 6 | 6 | 7 | 6 | 7 | 7 |
| 3           | 3    | 2                    | 8 | 3 | 3 | 8 | 3 | 3 | 2 | 2 | 3 | 3 | 2 | 1 | 3 | 2 | 1 | 3 | 2 | 3 |
| 0           | 0    | 8                    | 8 | 0 | 0 | 9 | 0 | 0 | 8 | 8 | 0 | 0 | 9 | 1 | 0 | 9 | 6 | 0 | 8 | 0 |
| 0           | 0    | 0                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0           | 0    | 0                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3           | 3    | 3                    | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| 5           | 5    | 5                    | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 |
| 1           | 1    | 2                    | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |

## **GENERAL BODY SYSTEM**

NONE

## **GENITAL SYSTEM**

## Clitoral Gland Adenoma

Ovary  
Carcinoma, Metastatic, Lung  
Leukemia Mononuclear  
Lymphoma Malignant

Uterus  
Lymphoma Malignant  
Polyp Stromal  
Endometrium, Adenoma

## **HEMATOPOIETIC SYSTEM**

## Bone Marrow

Lymph Node  
Mediastinal, Carcinoma, Metastatic, Lung  
Mediastinal, Leukemia Mononuclear

## Lymph Node, Mandibular

## Lymph Node, Mesenteric Leukemia Mononuclear

+  
Y

\* .. Total animals with tissue examined microscopically: Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

### I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically



TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

| FISCHER 344 RATS FEMALE<br>1.0 G/KG | DAY ON TEST<br>ANIMAL ID | females<br>(cont...) |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |
|-------------------------------------|--------------------------|----------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|
|                                     |                          | 0<br>7<br>3<br>0     | 0<br>7<br>2<br>8 | 0<br>6<br>8<br>8 | 0<br>7<br>3<br>0 | 0<br>4<br>8<br>9 | 0<br>7<br>3<br>0 | 0<br>7<br>2<br>8 | 0<br>7<br>3<br>0 | 0<br>7<br>1<br>1 | 0<br>1<br>3<br>0 | 0<br>6<br>2<br>9 | 0<br>6<br>1<br>6 | 0<br>7<br>3<br>0 | 0<br>7<br>8<br>8 | 0<br>6<br>1<br>6 | 0<br>7<br>3<br>0 | 0<br>7<br>2<br>9 | 0<br>7<br>3<br>0 | 0<br>7<br>2<br>8 | 0<br>6<br>7<br>7 |                  |                  |                  |
|                                     |                          | 0<br>0<br>0<br>0     | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 | 0<br>0<br>0<br>0 |                  |                  |                  |
|                                     |                          | 3<br>3<br>5<br>1     | 3<br>3<br>5<br>2 | 3<br>3<br>5<br>3 | 3<br>3<br>5<br>4 | 3<br>3<br>5<br>5 | 3<br>3<br>5<br>6 | 3<br>3<br>5<br>7 | 3<br>3<br>5<br>8 | 3<br>3<br>5<br>9 | 3<br>3<br>6<br>0 | 3<br>3<br>6<br>1 | 3<br>3<br>6<br>2 | 3<br>3<br>6<br>3 | 3<br>3<br>6<br>4 | 3<br>3<br>6<br>5 | 3<br>3<br>6<br>6 | 3<br>3<br>6<br>7 | 3<br>3<br>6<br>8 | 3<br>3<br>6<br>9 | 3<br>3<br>7<br>0 | 3<br>3<br>7<br>1 | 3<br>3<br>7<br>2 | 3<br>3<br>7<br>3 |

Alveolar/Bronchiolar Adenoma

X

Alveolar/Bronchiolar Carcinoma

X

Leukemia Mononuclear

X

Mediastinum, Schwannoma Malignant

Nose

+ +

Pleura

+

Trachea

+ +

## SPECIAL SENSES SYSTEM

Ear

+

Neural Crest Tumor

X

Eye

+ +

Harderian Gland

+ +

Zymbal's Gland

Adenoma

## URINARY SYSTEM

Kidney

+ +

Leukemia Mononuclear

X

Urinary Bladder

+ +

## SYSTEMIC LESIONS

\* .. Total animals with tissue examined microscopically; Total animals with tumor

M .. Missing tissue

+ .. Tissue examined microscopically

A .. Autolysis precludes evaluation

X .. Lesion present

BLANK .. Not examined microscopically

I .. Insufficient tissue

TDMS No. 20007 - 05

**Test Type: CHRONIC**

## **Route: GAVAGE**

**Species/Strain:** RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

## Kava kava extract

CAS Number: 9000-38-8

**Date Report Requested:** 09/21/2010

**Time Report Requested:** 09:10:56

**First Dose M/F:** 08/18/04 / 08/19/04

## Lab: BAT

| FISCHER 344 RATS FEMALE<br>1.0 G/KG | DAY ON TEST |                      |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|-------------------------------------|-------------|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
|                                     |             | females<br>(cont...) |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|                                     |             | ANIMAL ID            |   | 0 |   | 0 |   | 0 |   | 0 |   | 0 |   | 0 |   | 0 |   | 0 |   | 0 |   | 0 |   | 0 |   |   |
|                                     |             | 0                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|                                     |             | 7                    | 7 | 6 | 7 | 7 | 4 | 7 | 7 | 7 | 7 | 7 | 7 | 1 | 7 | 6 | 6 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 6 |
|                                     |             | 3                    | 2 | 8 | 3 | 3 | 8 | 3 | 3 | 2 | 2 | 3 | 3 | 2 | 1 | 3 | 2 | 1 | 3 | 2 | 3 | 2 | 3 | 3 | 2 | 8 |
|                                     |             | 0                    | 8 | 8 | 8 | 0 | 0 | 9 | 0 | 0 | 8 | 8 | 0 | 9 | 1 | 0 | 9 | 6 | 0 | 8 | 0 | 9 | 0 | 8 | 7 |   |
|                                     |             | 0                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
|                                     |             | 0                    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
|                                     |             | 3                    | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |   |
|                                     |             | 5                    | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 |   |
|                                     |             | 1                    | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 |   |

Multiple Organ  
Leukemia Mononuclear  
Lymphoma Malignant

**females  
(cont...)**

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

### I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

| FISCHER 344 RATS FEMALE | 1.0 G/KG | ANIMAL ID | DAY ON TEST                |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            | * TOTALS                   |
|-------------------------|----------|-----------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
|                         |          |           | 0<br>7<br>2<br>8           | 0<br>7<br>3<br>0           | 0<br>7<br>2<br>4           | 0<br>6<br>3<br>0           | 0<br>7<br>2<br>9           | 0<br>6<br>5<br>4           | 0<br>7<br>2<br>9           | 0<br>1<br>4<br>8           | 0<br>1<br>3<br>0           | 0<br>7<br>3<br>0           | 0<br>7<br>2<br>1           | 0<br>7<br>2<br>8           | 0<br>3<br>0                | 0<br>7<br>2<br>9           | 0<br>7<br>2<br>9           | 0<br>7<br>3<br>0           | 0<br>7<br>2<br>9           | 0<br>7<br>3<br>0           | 0<br>7<br>3<br>9           | 0<br>5<br>5<br>9           |                            |
|                         |          |           | 0<br>0<br>0<br>3<br>7<br>6 | 0<br>0<br>0<br>3<br>7<br>7 | 0<br>0<br>0<br>3<br>8<br>8 | 0<br>0<br>0<br>3<br>8<br>9 |

## ALIMENTARY SYSTEM

|                           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Esophagus                 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Cecum    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Colon    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Rectum   | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Ileum    | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Jejunum  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Liver                     | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Leukemia Mononuclear      | X | X | X |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 9  |
| Lymphoma Malignant        |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1  |
| Mesentery                 | + |   | + |   |   |   | + |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 9  |
| Pancreas                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Salivary Glands           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Stomach, Forestomach      | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Stomach, Glandular        | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Tooth                     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 2  |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

| FISCHER 344 RATS FEMALE | 1.0 G/KG | DAY ON TEST |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        |        | * TOTALS |        |        |
|-------------------------|----------|-------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|----------|--------|--------|
|                         |          |             | 0<br>7 | 0<br>7 | 0<br>7 | 0<br>6 | 0<br>7 | 0<br>2 | 0<br>6 | 0<br>7 | 0<br>1 | 0<br>1 | 0<br>7 | 0<br>7 | 0<br>7 | 0<br>7 | 0<br>3 | 0<br>2 | 0<br>9 | 0<br>7 | 0<br>7 | 0<br>3 | 0<br>5   |        |        |
| ANIMAL ID               |          |             | 0<br>2 | 3<br>8 | 2<br>0 | 3<br>9 | 3<br>0 | 6<br>4 | 3<br>9 | 6<br>5 | 3<br>4 | 9<br>8 | 4<br>0 | 3<br>0 | 3<br>0 | 3<br>0 | 2<br>1 | 2<br>8 | 2<br>0 | 9<br>9 | 2<br>9 | 3<br>0 | 2<br>9   | 3<br>9 | 5<br>9 |
|                         |          |             | 0<br>0   | 0<br>0 |        |
|                         |          |             | 0<br>0   | 0<br>0 |        |
|                         |          |             | 3<br>3   | 4<br>4 |        |
|                         |          |             | 7<br>7 | 7<br>7 | 7<br>7 | 8<br>8 | 9<br>9   | 0<br>0 |        |
|                         |          |             | 6<br>6 | 7<br>7 | 8<br>8 | 9<br>9 | 0<br>0 | 1<br>1 | 2<br>2 | 3<br>3 | 4<br>4 | 5<br>5 | 6<br>6 | 7<br>7 | 8<br>8 | 9<br>9 | 0<br>0 | 1<br>1 | 2<br>2 | 3<br>3 | 4<br>4 | 5<br>5 | 6<br>6   | 7<br>7 | 8<br>8 |

## CARDIOVASCULAR SYSTEM

|  |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |   |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|---|
| Blood Vessel                           | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |
| Heart                                  | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |
| Leukemia Mononuclear                   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 |
| Schwannoma Malignant, Metastatic, Lung |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 |

## ENDOCRINE SYSTEM

|                            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |   |
|----------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|---|
| Adrenal Cortex             | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |
| Leukemia Mononuclear       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 4 |
| Adrenal Medulla            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |
| Leukemia Mononuclear       |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 3 |
| Pheochromocytoma Benign    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 |
| Islets, Pancreatic         | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |
| Parathyroid Gland          | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | 47 |   |
| Adenoma                    |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 |
| Pituitary Gland            | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |
| Pars Distalis, Adenoma     |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 8 |
| Thyroid Gland              | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |
| Bilateral, C-cell, Adenoma |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 |
| C-cell, Adenoma            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 4 |
| Follicular Cell, Adenoma   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    | 1 |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

DAY ON TEST

## FISCHER 344 RATS FEMALE

1.0 G/KG

ANIMAL ID

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
| 7 | 7 | 7 | 7 | 7 | 6 | 6 | 7 | 2 | 6 | 7 | 7 | 1 | 1 | 0 | 7 | 7 | 7 | 7 | 3 | 0 | 7 | 7 | 7 | 3 | 5 |
| 2 | 3 | 2 | 3 | 6 | 3 | 2 | 6 | 9 | 2 | 2 | 9 | 4 | 3 | 3 | 3 | 2 | 2 | 8 | 2 | 9 | 0 | 2 | 3 | 9 | 5 |
| 8 | 0 | 9 | 0 | 4 | 0 | 9 | 5 | 4 | 9 | 8 | 4 | 0 | 0 | 0 | 0 | 1 | 8 | 0 | 9 | 2 | 9 | 0 | 9 | 9 |   |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |   |
| 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |   |
| 7 | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 |   |
| 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |   |

\* TOTALS

## GENERAL BODY SYSTEM

NONE

## GENITAL SYSTEM

Clitoral Gland  
Adenoma

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|---|
| + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | 49 |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |    | 1 |

Ovary  
Carcinoma, Metastatic, Lung  
Leukemia Mononuclear  
Lymphoma Malignant

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |   |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|---|---|
| + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |    | 1 |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |    | 1 |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |    |   | 1 |

Uterus  
Lymphoma Malignant  
Polyp Stromal  
Endometrium, Adenoma

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|---|
| + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |    | 1 |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |    | 8 |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |    | 1 |

## HEMATOPOIETIC SYSTEM

Bone Marrow

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|---|
| + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | 1 |   |   |   |   |   |    | 1 |

Lymph Node  
Mediastinal, Carcinoma, Metastatic, Lung  
Mediastinal, Leukemia Mononuclear

|   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |   |  |  |  |  |  |   |   |
|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|---|--|--|--|--|--|---|---|
| + |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   |   |  |  |  |  |  | 2 |   |
|   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | X |   |  |  |  |  |  | 1 |   |
|   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   | X |  |  |  |  |  |   | 1 |

Lymph Node, Mandibular

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | 0 |  |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |  |

Lymph Node, Mesenteric  
Leukemia Mononuclear

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |    |   |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|---|
| + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   | X |   |   |   |   |   |    | 5 |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

| FISCHER 344 RATS FEMALE                | DAY ON TEST |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |    | * TOTALS |
|--|-------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----|----------|
|  |             | 0<br>7<br>2<br>8           | 0<br>7<br>3<br>0           | 0<br>7<br>2<br>4           | 0<br>6<br>3<br>0           | 0<br>7<br>2<br>9           | 0<br>6<br>5<br>4           | 0<br>7<br>2<br>9           | 0<br>1<br>4<br>8           | 0<br>1<br>3<br>0           | 0<br>7<br>3<br>0           | 0<br>7<br>2<br>1           | 0<br>7<br>2<br>8           | 0<br>3<br>0                | 0<br>7<br>2<br>9           |    |          |
| 1.0 G/KG                               | ANIMAL ID   | 0<br>0<br>0<br>3<br>7<br>6 | 0<br>0<br>0<br>3<br>7<br>7 | 0<br>0<br>0<br>3<br>8<br>8 | 0<br>0<br>0<br>3<br>8<br>9 | 0<br>0<br>0<br>3<br>8<br>0 | 0<br>0<br>0<br>3<br>8<br>1 | 0<br>0<br>0<br>3<br>8<br>2 | 0<br>0<br>0<br>3<br>8<br>3 | 0<br>0<br>0<br>3<br>8<br>4 | 0<br>0<br>0<br>3<br>8<br>5 | 0<br>0<br>0<br>3<br>8<br>6 | 0<br>0<br>0<br>3<br>8<br>7 | 0<br>0<br>0<br>3<br>8<br>8 | 0<br>0<br>0<br>3<br>8<br>9 | 0<br>0<br>0<br>3<br>8<br>0 | 0<br>0<br>0<br>3<br>8<br>1 | 0<br>0<br>0<br>3<br>8<br>2 | 0<br>0<br>0<br>3<br>8<br>3 | 0<br>0<br>0<br>3<br>8<br>4 | 0<br>0<br>0<br>3<br>8<br>5 | 0<br>0<br>0<br>3<br>8<br>6 | 0<br>0<br>0<br>3<br>8<br>7 | 0<br>0<br>0<br>3<br>8<br>8 | 0<br>0<br>0<br>3<br>8<br>9 | 0<br>0<br>0<br>3<br>8<br>0 |    |          |
| Lymphoma Malignant                     |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            | X                          |    | 1        |
| Spleen                                 |             | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | 50 |          |
| Carcinoma, Metastatic, Lung            |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |    | 1        |
| Leukemia Mononuclear                   |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |    | 9        |
| Lymphoma Malignant                     |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |    | 1        |
| Thymus                                 |             | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | M                          | 48 |          |
| Leukemia Mononuclear                   |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |    | 1        |
| Lymphoma Malignant                     |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |    | 1        |
| Schwannoma Malignant, Metastatic, Lung |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |    | 1        |
| <b>INTEGUMENTARY SYSTEM</b>            |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |    |          |
| Mammary Gland                          |             | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | 50 |          |
| Fibroadenoma                           |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |    | 4        |
| Skin                                   |             | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | 50 |          |
| <b>MUSCULOSKELETAL SYSTEM</b>          |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |    |          |
| Bone                                   |             | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | 50 |          |
| <b>NERVOUS SYSTEM</b>                  |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |    |          |
| Brain                                  |             | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | 50 |          |
| Granular Cell Tumor Benign             |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |    | 1        |
| <b>RESPIRATORY SYSTEM</b>              |             |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |                            |    |          |
| Lung                                   |             | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | +                          | 50 |          |

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

TDMS No. 20007 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

## P04: NEOPLASMS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

| FISCHER 344 RATS FEMALE   | 1.0 G/KG | DAY ON TEST | ANIMAL ID |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |             |                  |                  |                  |                  |                  |                  |                  |                  |  |  | * TOTALS |    |    |    |
|---|----------|-------------|-----------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|-------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|--|--|----------|----|----|----|
|   |          |             |           | 0<br>7<br>2<br>8 | 0<br>7<br>3<br>0 | 0<br>7<br>2<br>4 | 0<br>6<br>3<br>0 | 0<br>7<br>2<br>9 | 0<br>6<br>5<br>4 | 0<br>7<br>2<br>9 | 0<br>1<br>4<br>8 | 0<br>1<br>3<br>0 | 0<br>1<br>3<br>0 | 0<br>7<br>3<br>0 | 0<br>7<br>2<br>1 | 0<br>7<br>2<br>8 | 0<br>3<br>0 | 0<br>7<br>2<br>9 |  |  |          |    |    |    |
| Alveolar/Bronchiolar Adenoma  |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |             |                  |                  |                  |                  |                  |                  |                  |                  |  |  | 1        |    |    |    |
| Alveolar/Bronchiolar Carcinoma  |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |             |                  |                  |                  |                  |                  |                  |                  |                  |  |  | 1        |    |    |    |
| Leukemia Mononuclear  |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |             |                  |                  |                  |                  |                  |                  |                  |                  |  |  | 5        |    |    |    |
| Mediastinum, Schwannoma Malignant   |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |             |                  |                  |                  |                  |                  |                  |                  |                  |  |  | 1        |    |    |    |
| Nose  |          |             |           | X                |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |             |                  |                  |                  |                  |                  |                  |                  |                  |  |  | X        | 50 |    |    |
| Pleura  |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |             |                  |                  |                  |                  |                  |                  |                  |                  |  |  |          |    | 1  |    |
| Trachea   |          |             |           | X                |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |             |                  |                  |                  |                  |                  |                  |                  |                  |  |  |          |    | 50 |    |
| <b>SPECIAL SENSES SYSTEM</b>  |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |             |                  |                  |                  |                  |                  |                  |                  |                  |  |  |          |    |    |    |
| Ear   |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |             |                  |                  |                  |                  |                  |                  |                  |                  |  |  |          |    | 1  |    |
| Neural Crest Tumor  |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |             |                  |                  |                  |                  |                  |                  |                  |                  |  |  |          |    | 1  |    |
| Eye   |          |             |           | X                |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |             |                  |                  |                  |                  |                  |                  |                  |                  |  |  |          |    | 50 |    |
| Harderian Gland   |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |             |                  |                  |                  |                  |                  |                  |                  |                  |  |  |          |    | 50 |    |
| Zymbal's Gland  |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |             |                  |                  |                  |                  |                  |                  |                  |                  |  |  |          |    | 1  |    |
| Adenoma   |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |             |                  |                  |                  |                  |                  |                  |                  |                  |  |  |          |    | X  | 1  |
| <b>URINARY SYSTEM</b>   |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |             |                  |                  |                  |                  |                  |                  |                  |                  |  |  |          |    |    |    |
| Kidney  |          |             |           | X                |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |             |                  |                  |                  |                  |                  |                  |                  |                  |  |  |          |    | 50 |    |
| Leukemia Mononuclear  |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |             |                  |                  |                  |                  |                  |                  |                  |                  |  |  |          |    |    | 2  |
| Urinary Bladder   |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |             |                  |                  |                  |                  |                  |                  |                  |                  |  |  |          |    |    | 50 |
| <b>SYSTEMIC LESIONS</b>   |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |             |                  |                  |                  |                  |                  |                  |                  |                  |  |  |          |    |    |    |
| * .. Total animals with tissue examined microscopically; Total animals with tumor |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |             |                  |                  |                  |                  |                  |                  |                  |                  |  |  |          |    |    |    |
| + .. Tissue examined microscopically  |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |             |                  |                  |                  |                  |                  |                  |                  |                  |  |  |          |    |    |    |
| X .. Lesion present   |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |             |                  |                  |                  |                  |                  |                  |                  |                  |  |  |          |    |    |    |
| I .. Insufficient tissue  |          |             |           |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |             |                  |                  |                  |                  |                  |                  |                  |                  |  |  |          |    |    |    |

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Kava kava extract

CAS Number: 9000-38-8

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Lab: BAT

| FISCHER 344 RATS FEMALE<br>1.0 G/KG | DAY ON TEST<br>ANIMAL ID |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |    | * TOTALS |
|-------------------------------------|--------------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|----|----------|
|                                     |                          | 0<br>7<br>2<br>8 | 0<br>7<br>3<br>0 | 0<br>7<br>2<br>4 | 0<br>6<br>3<br>0 | 0<br>7<br>2<br>9 | 0<br>6<br>9<br>5 | 0<br>7<br>2<br>4 | 0<br>7<br>2<br>9 | 0<br>1<br>4<br>8 | 0<br>1<br>3<br>4 | 0<br>7<br>3<br>0 | 0<br>7<br>2<br>1 | 0<br>7<br>2<br>8 | 0<br>7<br>3<br>0 | 0<br>7<br>2<br>9 | 0<br>7<br>3<br>0 | 0<br>7<br>2<br>9 | 0<br>7<br>3<br>0 | 0<br>7<br>2<br>9 | 0<br>7<br>3<br>0 | 0<br>7<br>2<br>9 | 0<br>7<br>3<br>0 | 0<br>7<br>3<br>0 |    |          |
| Multiple Organ                      |                          | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | +                | 50 |          |
| Leukemia                            |                          |                  |                  | X                |                  | X                |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |    | 9        |
| Mononuclear                         |                          |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |    | 1        |
| Lymphoma                            |                          |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |    |          |
| Malignant                           |                          |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |                  |    |          |

\*\*\* END OF REPORT \*\*\*

\* .. Total animals with tissue examined microscopically; Total animals with tumor

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically